UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA Plaintiff, v. B4B EARTH TEA LLC, a limited liability company; B4B CORP., a corporation; and ANDREW MARTIN SINCLAIR, individually and as an officer of B4B EARTH TEA LLC and B4B CORP., Defendants.	**Civil Action No.: 22-CV-1159**

EXPERT REPORT OF DR. MARITON DANIEL DOS SANTOS

I. QUALIFICATIONS

I am an Interdisciplinary Scientist in the Office of Dietary Supplement Programs ("ODSP") in the Center for Food Safety and Applied Nutrition ("CFSAN") at the United States Food and Drug Administration ("FDA"). I have held this position since 2012.

In my capacity as an Interdisciplinary Scientist, I have worked as a Biologist and Toxicology Reviewer and as an advisor to the ODSP Director. My work at FDA has required me to review product labeling, scientific studies, clinical trials, and other data for a variety of drugs and dietary supplements. Specifically, as part of my duties at FDA, I review product labeling and conduct thorough and comprehensive searches of publicly-available medical and scientific literature to determine whether a product is a drug, a new drug, an unapproved new drug, and/or a prescription drug under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. I also assist in the formulation of policy and scientific guidelines concerning dietary ingredients, assess the medical significance and public health impact of adverse events related to drugs and dietary supplements, and develop consumer surveys to determine whether claims made on dietary supplement products are misleading. Finally, I provide scientific guidance to industry and facilitate discussions between FDA and industry regarding compliance with the FDCA.

By virtue of my training and professional experience, I am familiar with and knowledgeable about the FDCA's requirements and FDA's enforcement policies pertaining to drugs, new drugs, and unapproved new drugs. I am familiar with disease claims (*i.e.*, claims that a product is intended for use in diagnosing, curing, mitigating, treating, or preventing a disease), the quantity and quality of evidence that is needed to establish the safety and effectiveness of drugs, criteria for adequate and well-controlled clinical trials, the standards for evaluating whether a drug is generally recognized as safe and effective ("GRAS/E") by qualified experts for its intended use, the determination of whether a drug is approved by FDA for its intended use, and the determination of whether a disease intended to be treated by a drug requires diagnosis and management of a physician such that it is a prescription drug.

From September 2012 to December 2013, I worked as an FDA contractor under the Oak Ridge Institute for Science and Education program, which recruits outside scientists to work at FDA. In that capacity, I performed many of the tasks described above.

Prior to joining FDA, I worked as a Physiologist and Pharmacologist Researcher for the U.S. Army Medical Research Institute of Chemical Defense ("USAMRICD") from December 2009 to September 2012. At USAMRICD, I was involved in research projects evaluating the mechanisms of toxicity of chemical nerve agents in mammals.

From September 2002 to October 2009, I was a postdoctoral fellow at the University of Maryland's School of Medicine (Baltimore), where my research focused on neurophysiology.

I received my Ph.D. in biological science in 2002 from the Federal University of Rio de Janeiro, Rio de Janeiro, Brazil; my M.S. in biophysics in 1996 from the same university; and my Pharm.D. in 1992 from the Federal University of Maranhao, Sao Luiz, Brazil.

I am making this report in *United States v. B4B Earth Tea, LLC*, Case No. 22-CV-1159 (E.D.N.Y).

Please see my curriculum vitae (attached to this report – *Attachment 3*) for a full statement of my qualifications.

II. STATEMENT OF OPINIONS

It is my expert opinion, based on my training and experience regarding drugs that: (1) B4B Earth Tea's products are drugs under the FDCA because they are intended for use in curing, mitigating, treating, and/or preventing diseases, including but not limited to COVID-19; (2) B4B Earth Tea's products are new drugs under the FDCA because they are not GRAS/E for their intended uses; and (3) B4B Earth Tea's products are unapproved new drugs under the FDCA because they are not the subject of an FDA-approved new drug application ("NDA"), abbreviated new drug application ("ANDA"), or effective investigational new drug application ("IND"). The bases of my opinions are set out in the following sections, respectively.

A. B4B EARTH TEA'S PRODUCTS ARE DRUGS

Under the FDCA (21 U.S.C. § 321(g)(1)), the term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). Therefore, whether a product is a "drug" under the FDCA depends on its intended use. The intended use of a product may be determined from any relevant source, including labels, labeling, and the circumstances surrounding the distribution of the article.

Claims about diagnosing, curing, mitigating, treating, or preventing a disease are generally referred to as "disease claims." See 21 C.F.R. § 101.93(g). A "disease" is "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that disease resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition." 21 C.F.R. § 101.93(g)(1). The use of a disease claim in product labels and/or labeling causes a product to be a drug under the FDCA, regardless of whether it bears a disclaimer that FDA has not evaluated the claim. Moreover, even if evidence existed that might support a disease claim, the claim is still deemed unlawful without FDA's evaluation of the safety and effectiveness of the claimed uses. Thus, evidence that a product is intended to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases causes that product to be a drug under the FDCA.

B4B Earth Tea's product labeling states that such products are intended for use in diagnosing, curing, mitigating, treating, and/or preventing a wide variety of diseases, ranging from COVID-19 to several types of Cancer and HIV, as well as pain relief, etc. Defendant's product labeling contains numerous disease claims, including the following, for example:

> "EARTH TEA PROVEN NATURAL TREATEMENT FOR COVID-19.. BY B4B CORP WORK IN MINUTES GET U FEELING NORMAL WITHIN 24HRS.. EARTHTEA.US #COVID19 #CORONAVIRUS" (August 4, 2020) [*Screenshot:* **USA-B4B00003138**]

"We are 100% sure Earth Tea gets rid of #Covid19 #coronavirus and it does it Fast on big question now is can it be considered a vaccine. From one result it shows it can protect…" September 1, 2020) [*Screenshot:* **USA-B4B00003212**]

"Covid19 Stopper Movement @b4bcorpusa– #COVID19STOPPER one Bottle is all it takes..and you'll be back to normal fast. Quarantine? Bypass that with Earth Tea..100% fighters that fights virus because plants knows how to fight bacteria.. Kids safe, teen safe & adult safe. We are the #One #covid19" (September 15, 2020) [*Screenshot:* **USA-B4B00003214**]

"Facts #vaccines VS EARTHTEAEXTRASTRENGTH Vaccines trials show preventing hospitalization is 85-96% while so far Earth Tea Extra Strength is 100% we have helped people who are vaccinated. No one who was positive and used Earth Tea went to hospital. Www. earthtea.US" (September 10, 2021) [*Screenshot:* **USA-B4B00003555**]

"To all #College campus you can solve covid issues by having students use Earth Tea Extra Strength… It can be drank as is mixed with juice but immediately change the course of Covid19 with just one mouth full. We can guarantee that." (December 15, 2021) [**USA-B4B00003275**]

"If you're battling covid give Earth Tea Extra Strength a shot for 2 days and you will be able to walk like it never happened. With 2 hours you will feel the changes start to happen after just half bottle. By the time you finish 1 bottle you will feel better then #2 is a charm." (December 30, 2021) [*Screenshot:* **USA-B4B00003273**]

"Earth Tea Extra Strength the world's most powerful natural supplement. After we tackle #Covid19 with our Clinical Trials that should begin anytime now, we would like to try Earth Tea Extra Strength Against every known illness known to mankind. Whether It's #Arthritis, #asthma, #insomnia, #overdose, #cancer, #HIV, #lungs issues, #kidneystones, etc. Earth Tea Extra Strength helps your body fight…" (April 15, 2021) [*Screenshot:* **USA-B4B00003532**]

"b4bearthteallc Know anyone with HIV or Cancer? We would like to try 1/2 gallon of Earth Tea Extra Strength against #HIV AND #CANCER 2 cups per day for 5 days! #EARTH TEA Www.earthtea.US" (October 8, 2022) [*Screenshot:* **USA-B4B00003221**]

Therefore, based on their intended uses, I conclude that B4B Earth Tea's products are drugs within the meaning of 21 U.S.C. § 321(g)(1)(B). A more extensive list of examples of B4B Earth Tea's product labeling claims can be found in *Attachment 1.*

B. B4B EARTH TEA'S PRODUCTS ARE NEW DRUGS

A drug is a "new drug" when (1) "such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . ." or (2) "such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p)(1) and (2).

1. The GRAS/E Analysis

In order to be GRAS/E within the meaning of 21 U.S.C. § 321(p)(1), a drug must satisfy three criteria:

- First, the particular drug product must have been subjected to adequate and well-controlled clinical investigations to establish the product's safety and effectiveness.

- Second, those investigations must have been published in the scientific literature so that they are available to qualified experts.

- Third, experts must generally agree, based on those published studies, that the product is safe and effective for its intended uses. A product's general recognition as GRAS/E must be evidenced by at least the same quality and quantity of data as are necessary to support approval of an NDA.

I also took into account the FDA regulation at 21 C.F.R. § 314.126, which is the standard used to determine GRAS/E and which describes the characteristics of adequate and well-controlled clinical investigations. This regulation expresses many of the scientific principles underlying adequate and well-controlled clinical investigations. For a study to be adequate and well-controlled, it must: (a) enroll a sufficiently large number of adequately characterized study participants; (b) have at least one control group; minimize bias, usually through random assignments of study participants to control and treatment groups and through the blinding of participants and investigators to those assignments; and (c) analyze the results of the study adequately to assess the effects of the treatment. The purpose of requiring such rigorously controlled investigations is to ensure that patients receive only those drugs whose safety and effectiveness have been established by accepted scientific methods.

Assessing whether there is adequate clinical literature to support a determination of GRAS/E starts with searches of established medical literature databases PubMed[1], Medline[2], Embase[3], and ClinicalTrials.gov[4] for keywords.

Such searches can begin with the drug ingredient and include additional terms to limit search results to articles/studies involving the indication and dosage form under consideration. When available, product brand name and manufacturer name could be searched to help ensure that any published studies identified relate to the specific drug product at issue. Additionally, searching by

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[1] PubMed and MEDLINE are databases provided by the U.S. National Library of Medicine (NLM). PubMed includes over 35 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s. http://www.ncbi.nlm.nih.gov/pubmed

[2] MEDLINE is a "bibliographic database that contains more than 29 million references to journal articles in life sciences with a concentration on biomedicine." MEDLINE also contains citations to literature published from 1966 to the present, and may contain some older material. https://www.nlm.nih.gov/medline/index.html

[3] EMBASE is a biomedical database produced by Elsevier. The database contains bibliographic records with citations, abstracts and indexing derived from biomedical articles in peer reviewed journals and is especially strong in its coverage of drug and pharmaceutical research. EMBASE covers nearly 5,000 active journals, of which nearly 2,000 are unique compared with MEDLINE. http://www.Embase.com/home#/search:quickSearch

[4] ClinicalTrials.gov is a searchable database that provides information regarding ongoing publicly and privately supported clinical research studies. https://clinicaltrials.gov

specific types of studies, *i.e*., randomized and/or controlled, would specify the type and quality of the information that would be expected to be available to support a GRAS/E determination. Review of abstracts of studies meeting these search criteria would provide an overview of clinical literature that might support a GRAS/E determination. Additional review of the abstracts could result in the elimination of studies that would not support a GRAS/E determination for a drug product of a specific dosage form and strength, and for the particular indication at issue. Further, more detailed review of the full text of the article(s) to assess their relevance to a GRAS/E determination generally would be necessary only if the search criteria and review of the abstracts identify studies having the fundamental requirements for adequate and well-controlled studies. Literature searches that do not identify at least two adequate and well-controlled studies would likely exclude the possibility of a determination of GRAS/E status for any given drug product.

2. Literature Searches for this Report

On March 10, 2023, I searched PubMed/MEDLINE to identify any well-controlled clinical trials to support a determination that the products manufactured or marketed by B4B Earth Tea are GRAS/E. As indicated in **Table 1** below, I did not identify any well-controlled clinical trials to support a determination that any of the products manufactured or marketed by B4B Earth Tea are GRAS/E. Although the search for "B4B Corporation" located one result, review of that study revealed that the publication has nothing to do with the Defendants, their products, or tea. Rather, it concerns "mitochondrial haplogroups B2 and B4 with next-generation mitogenome sequencing to distinguish native American from Asian haplotypes." An abstract of the study is provided in *Attachment 2a* of this report. Similarly, when the search term "Earth Tea" was used without any filter or criteria, *i.e.,* without quotes, it resulted in 200 hits. Upon review, none of the 200 publications were applicable to this case. This is because the broad search terms captured publications containing the word "Earth" and/or "Tea." A printout showing the types of inapplicable publications identified using these search terms is provided in *Attachment 2a.*

Table 1 - PubMed/MEDLINE search results

Search #	Search Terms	Restrictions	Results	Applicable results
Search 1	B4B Corporation	None	1	0
Search 2	B4B Earth Tea LLC	None	0	0
Search 3	B4B Earth Tea	None	0	0
Search 4	Earth Tea	None	200	0
Search 5	Earth Tea Extra Strength	None	0	0

On March 10, 2023, I searched EMBASE to identify any well-controlled clinical trials to support a determination that the products manufactured or marketed by B4B Earth Tea are GRAS/E. See **Table 2** for search strategy and results. I did not identify any well-controlled clinical trials in EMBASE to support a determination that any of the products manufactured or marketed by B4B are GRAS/E. As indicated, three of the EMBASE searches had positive results. All three located the same publication: "An Open Label, Multicentre, Multi-Dose, Single Arm Treatment Clinical Trial to Determine the Safety and Efficacy of New Natural Health Drink of Earth Tea in Human Adult, Patients with Mild Covid-19." The study was authored by Martin Sinclair and published in the Journal of Pharmaceutical Negative Results in 2022. A copy of the paper is provided in *Attachment 2b*. I also discuss this publication in detail in item 3 below.

Table 2 - Embase search results

Search #	Search Terms	Restrictions	Results	Applicable results
Search 1	B4B Corporation	None	0	0
Search 2	B4B Earth Tea LLC	None	1	1
Search 3	B4B Earth Tea	None	1	1
Search 4	Earth Tea	None	1	1
Search 5	Earth Tea Extra Strength	None	0	0

On March 9, 2023, I searched ClinicalTrials.gov to identify any well-controlled clinical trials to support a determination that a product manufactured or marketed by B4B Earth Tea is GRAS/E. See **Table 3** for search strategy and results. I did not identify any well-controlled clinical trials in ClinicalTrials.gov to support a determination that any of the products manufactured or marketed by B4B Earth Tea are GRAS/E. A printout of this search result can be found in *Attachment 2c.*

Table 3 - ClinicalTrials.gov

Search #	Category	Search Terms	Results
Search 1	Sponsor/ Collaborator	B4B Corp.	0
Search 2	Sponsor/ Collaborator	B4B Corporation	0
Search 3	Sponsor/ Collaborator	B4B Earth Tea LLC	0
Search 4	Intervention/treatment	B4B Earth Tea	0
Search 5	Intervention/treatment	Earth Tea Extra Strength	0
Search 6	Intervention/treatment	Earth Tea	0

3. Review of the B4B Earth Tea Clinical Trial Publication

I have reviewed the clinical trial publication entitled *An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial To Determine The Safety And Efficacy Of Earth Tea* to determine if it provides sufficient data to support the claim that Earth Tea is a safe and effective treatment for COVID-19 (see *Attachment 2b*). The study was previously released on the B4B Earth Tea website https://b4bearthtea.com/earth-tea-extra-strength-clinical-trial/ as a clinical study report sponsored by Sinclair B4B Corp – Date 18 Sep 21 (See *Attachment 2* - screenshots B4B3_00000132-133) and finally published in 2022 in the *Journal of Pharmaceutical Negative Results | Volume 13 | Special Issue 9 | 2022*. The study's primary objective was to demonstrate the safety and efficacy of Earth Tea and also to test the safety and tolerability of multiple doses ingested by subjects who had been diagnosed with "mild" COVID-19.

This clinical study presents several weaknesses regarding how it might support the efficacy and safety of Earth Tea in the treatment of COVID-19. For example:

(1) For a clinical investigation or study to be adequately controlled, it must for example include: a sufficiently large and well characterized patient population; at least one control or placebo group; minimized bias, usually through random assignments to control and treatment groups and blinding of participants and/or investigators to those assignments; and an appropriate

statistical analysis of the study results that is adequate to assess the treatments' effects.[5] The B4B Earth Tea study did not meet any of these requirements. The B4B Earth Tea clinical trial study was conducted in an open-label fashion protocol, meaning study subjects and researchers are both aware of which treatment a patient is receiving. This type of study can be useful when used to compare different treatments or to gather additional information about a long-term effect of a drug in the intended patient population.[6] But, it is not adequate for establishing GRAS/E for a substance because both participants and researchers know what treatment is being given, which introduces bias, creating a condition in which participants might report more positive effects or fewer side effects if they believe they are receiving the test substance; and researchers might unconsciously interpret data in a way that favors the test substance.

It is also important to have enough subjects in a clinical study to be able to draw meaningful conclusions from the results. The number of subjects involved in the study sponsored by B4B (only 15 subjects) is not sufficient to reach a conclusion that Earth Tea is able to treat patients with COVID-19.

Also, the trial did not measure any long-term outcome effects (the duration of the study was 10 days while the study treatment duration was 4 to 5 days) and did not provide sufficient data to support the claim that Earth Tea is a safe and effective treatment for all known variants of COVID-19. Short-term studies might overlook side effects that take time to develop, and this could put participants at risk for unforeseen complications down the road. Overall, long-term clinical trials are vital for ensuring the safety and efficacy of new treatments over time. They provide crucial data that informs medical decisions and promotes responsible healthcare practices.

Additionally, it is not possible to determine if the results of this study, which involved only Asian subjects, could be extrapolated to other ethnic populations. For example, a drug that is effective in treating a certain condition in Asians may not be effective in treating the same condition in Caucasians or African Americans. This is because there are several factors that can affect how a drug or treatment works in different populations, including genetic differences, environmental factors, and lifestyle choices.

For these reasons, the Defendants' protocol does not reflect a solid clinical study and cannot be a reference for the scientific-medical community about the effectiveness of B4B Earth Tea as a treatment for patients infected by COVID-19.

(2) The patient treatment protocol with two doses (morning cold tea and hot tea 12 hours later) does not conform to the requirements for a test drug to be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation. Specifically, if the patient treatment protocol does not specify these requirements of the tea (drug) that is being administered to the patient, then it is not possible to determine the significance of the results of the investigation. This is because the results of the investigation could be due to factors other than the tea, such as the patient's underlying

[5] 21 C.F.R. § 314.126 - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=314.126
[6] Understanding clinical trial terminology: https://www.concertpharma.com/understanding-clinical-trial-terminology-what-is-an-open-label-clinical-trial/

medical condition or other medications that the patient was taking. Furthermore, the authors stated that the Earth Tea product "is made of a combination of natural vegetable," but they did not describe its manufacturing process.

(3) The authors claim that all 15 patients who received the investigational drug - Earth Tea - "*showed a significant reduction in clinical cure and micro biologically cure analysis on Day 02 of evaluation visit."* However, the authors did not demonstrate the physiological mechanism by which they claim their product reverses the subjects' clinical condition in less than 48 hours, as indicated in Graph-1of the published paper. According to CDC, people with COVID-19 may experience a wide range of symptoms that could appear 2-14 days after exposure to the virus. Thus, the study fails to address quantitative data on how long the subjects, with mild COVID-19, were sick; this information is crucial to verify whether the biological cure was a result of the Defendants' product's mechanism of action, or from the subjects' natural immunological system.

(4) Finally, the B4B Earth Tea clinical trial study was published in a journal (*Journal of Pharmaceutical Negative Results* – JPNR) that's main focus is to publish "theoretical and empirical paper[s] that report[] the negative findings and research failures in pharmaceutical field."[7] However, the Authors claimed that their clinical study had a positive outcome for treatment of patients with COVID-19, which contradicts the journal's main objective. Also, this journal displays a very low "impact factor (IF) = 0.39." The IF is useful in clarifying the significance of absolute (or total) citation frequencies of a study; the IF of a journal is calculated by dividing the number of current year citations to the source items published in that journal during the previous two years.[8] A high IF generally means that the journal is well-respected and publishes relevant and high-quality research. A low IF, on the other hand, means articles in that journal are cited and relied upon less frequently. According to **Resurchify** (www.resurchify.com), an electronic portal for calculating IF, Rank, and the Index of scientific journals, JPNR's rank and IF are very low among the scientific community. The table below compares the IF, Rank, and h-Index, of the JPNR with the current number one (1) journal (Ca-A Cancer Journal for Clinicians – Ca-ACJC) as of 2021:

Relevance	**Ca-ACJC**	**JPNR**
Overall Ranking	1	22,731
Impact Factor	186.75	**0.39**
h-Index*	182	6

*The h-index of a publication is the largest number h such that at least h articles in that publication were cited at least h times each. For example, a journal with a h-index of 20 has published 20 articles that have been cited 20 or more times (https://libraryguides.missouri.edu/impact/hindex).

I have also searched Web of Science[9] to identify whether the B4B Earth Tea clinical trial publication has been cited by other publications in the field of COVID-19 treatment. No records

[7] Journal of Pharmaceutical Negative Results - https://www.pnrjournal.com/index.php/home/about
[8] Clarivate Impact Factor - https://clarivate.com/webofsciencegroup/essays/impact-factor/
[9] Web of Science is a multidisciplinary resource for searching, accessing, and analyzing journal literature. It provides a comprehensive citation search and covers over 90 million records from scientific journals indexed from as early as 1900 to the present. https://www.webofscience.com/

were found. In my search criteria, I used the title of the article as well as the author names (*Rajaganapathy K* or *Martin S or B4B Earth Tea*). A printout of the research result can be found in *Attachment 2d*. Currently, there are thousands of studies being done on COVID-19; more precisely, Clinical.gov and PUBMED display a total of 8829 and 3372 studies for COVID-19 respectively, as of March 15, 2023, and none of these studies have cited B4B Earth Tea's findings.

All of these shortcomings indicate that the B4B clinical study has little, or no scientific impact and Earth Tea is not generally recognized by the scientific/medical community as an effective therapeutic treatment for patients with COVID-19. Therefore, this single study is insufficient to support the efficacy and safety of the B4B Earth Tea products.

4. Conclusion of GRAS/E Analysis

Because there are no well-controlled clinical trials to support a determination that any of the products manufactured or marketed by B4B Earth Tea are GRAS/E for any intended use(s), and based on my training and professional experience in the evaluation of the safety and effectiveness of drugs, I conclude that B4B Earth Tea products are not generally recognized among qualified experts as safe and effective for their intended use(s). 21 U.S.C. § 321(p)(1).

C. B4B EARTH TEA'S PRODUCTS ARE UNAPPROVED NEW DRUGS

Sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), provide that a new drug may not be introduced into or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for the drug.

When a sponsor submits to FDA an Abbreviated New Drug Application ("ANDA"), an Investigational New Drug Application ("IND"), or New Drug Application ("NDA") for any intended use of a new drug, the existence of that submission is reflected in various records that FDA regularly makes and preserves in the normal course of its regulatory affairs.

On March 9, 2023, I conducted diligent searches of the official FDA records[10] to determine whether B4B Earth Tea has sought approval for any of B4B Earth Tea's products, and to determine if any of the products has been approved in the United States. The searches identified no ANDAs, INDs or NDAs associated with B4B Earth Tea. Additionally, the firm has not sought approval for any of the Earth Tea products. See **Tables 4**, **5** and **6** for search strategy and results.

Table 4 - FDA Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) database (see printout of this search result in *Attachment 2e)*

Search #	Product Name	Application type ANDA, and IND, and NDA
Search 1	B4B Earth Tea	0
Search 2	Earth Tea Extra Strength	0
Search 3	Earth Tea	0
Search #	**Sponsor Name (Company)**	**Application type ANDA, and IND, and NDA**

[10] The following FDA Databases were searched: (a) Document Archiving, Reporting, and Regulatory Tracking System (DARRTS); (b) Drugs@FDA; and (c) FDA Orange Book.

Search 4	B4B Corp.	0
Search 5	B4B Corporation	0
Search 6	B4B Earth Tea LLC	0

Table 5 - Drugs@FDA (see print out of this search result in *Attachment 2f)*

Search #	Drug Name/Active Ingredient/Application Number	# of records identified
Search 1	B4B Earth Tea	0
Search 2	Earth Tea Extra Strength	0
Search 3	Earth Tea	0

Table 6 - FDA Orange Book (see print out of this search result in *Attachment 2g)*

Search #	Search Terms for Proprietary Name, Active Ingredient	Results	Applicable results
Search 1	Earth Tea	0	0
Search 2	Earth Tea Extra Strength	0	0
Search 3	B4B Earth Tea	0	0
Search #	**Applicant (Company)**	**Results**	**Applicable results**
Search 4	B4B Corp.	0	0
Search 5	B4B Corporation	0	0
Search 6	B4B Earth Tea LLC	0	0

Since there are no approved applications associated with B4B Earth Tea, I conclude that the Earth Tea products are unapproved new drugs.

III. CONCLUSION

Based on my review discussed above, as well as my background, training, and experience, I conclude that:

- B4B Earth Tea's products are drugs under the FDCA because they are intended for use in curing, mitigating, treating, and/or preventing diseases, including but not limited to "COVID-19" and other types of diseases.

- B4B Earth Tea's products are new drugs under the FDCA because they are not GRAS/E for their intended uses.

- And B4B Earth Tea's products are unapproved new drugs under the FDCA because they are not the subject of an FDA-approved new drug application ("NDA"), abbreviated new drug application ("ANDA"), or effective investigational new drug application ("IND").

IV. ATTACHMENTS

1. Attachment 1: B4B Earth Tea's product labeling claims
2. Attachment 2: Results from searches of scientific literature databases
3. Curriculum vitae

V. EXIBITS USED TO SUPPORT OPINION

No exhibits are anticipated at this time beyond the material reviewed, cited and included in this report.

VI. MATERIAL REVIEWED

1. I have reviewed numerous screenshots concerning B4B Earth Tea's products. Specifically, I reviewed label and labeling for B4B Earth Tea's products ("Earth Tea" and "Earth Tea Extra Strength") including:
   - Screenshots of Twitter posts from B4B's Twitter accounts:
     - Stopper Movement @b4bcorpusa
     - Head Gone ® Earth Tea @headgone
     - B4B Earth Tea LLC @b4bearthteallc
   - Screenshots of B4B Facebook posts at www.facebook.com/b4bcorpUSA
   - Screenshots of B4B Instagram posts @b4bearthteallc
   - Screenshots of B4B official website: https://b4bcorp.com
   - Videos produced by the defendants/consumers and displayed on the B4B Earth Tea website and social media

2. Federal Food, Drug, and Cosmetic Act, regulations, statutes, and other laws referred to herein.

3. Other material as cited or referenced in this Report.

The screenshots were collected and provided by the U.S. Department of Justice and they are dated from Aug 2020 to Dec 2022. Two electronic folders were shared with me named as: (1) COVID; and (2) Other Diseases.

VII. OTHER AREAS OF POSSIBLE TESTIMONY

I may offer testimony on topics within my field of expertise and which are not currently known but may be adduced at trial as the evidence develops. I will also be prepared to offer rebuttal testimony. This testimony will be dependent on an evaluation of the testimony on similar topics offered by a witness called by the opposing party.

VIII. COMPENSATION

I am not being compensated for my work in this case beyond my normal government salary.

IX. PRIOR EXPERT TESTIMONY

I have not testified by deposition or at trial in any case in the previous four years.

X. PUBLICATIONS

The following is a complete list of all publications that I have authored in the previous ten years:

1. Sunggu Yang, **Mariton D. Santos**, Cha-Min Tang, Jae Geun Kim and Sungchil Yang. A Postsynaptic Role for Short-Term Neuronal Facilitation in Dendritic Spines. *Front. Cell. Neurosci.*, 30 September 2016 | http://journal.frontiersin.org/article/10.3389/fncel.2016.00224/full

2. Benjamin Wong, Michael W. Perkins, **Mariton D. Santos**, Ashley M. Rodriguez, Gleeson Murphy, and Alfred M. Sciuto. Development of a model for nerve agent inhalation in conscious rats. *Toxicol Mech Methods*, Published online 23 May 2013; Early Online: 1– 11; Online ISSN 1537-6524 (electronic).

3. **Mariton D. Santos**, Michael H. Mohammadi, Sunggu Yang, Conrad W. Liang, Joseph P.Y. Kao, Bradley E. Alger, Scott M. Thompson, Cha-Min Tang. Dendritic Hold and Read: A gated mechanism for short term information storage and retrieval. *PLoS One*. 2012;7(5):e37542

XI. SUPPLEMENTATION

I reserve the right to supplement this report or my testimony.

Dated: April 18 2024.

Mariton Daniel dos Santos, *Ph.D., Pharm.D.*
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
The Office of Dietary Supplement Programs (ODSP)
Division of Policy and Regulations Implementation (DPRI)
Regulations Implementation Branch (RIB)

ATTACHMENT 1

B4B Earth Tea's Product Labeling Claims

The claims listed below represent a small sample of hundreds of claims collected from B4B Earth Tea's social media and website.

I. COVID-19 Claims

A - *From the B4B Twitter account:* ***Stopper Movement @b4bcorpusa***

1. **USA-B4B00003138**: "EARTH TEA PROVEN NATURAL TREATEMENT FOR COVID-19.. BY B4B CORP WORK IN MINUTES GET U FEELING NORMAL WITHIN 24HRS.. EARTHTEA.US #COVID19 #CORONAVIRUS" [Aug 4, 2020]

2. **USA-B4B00003143:** "Got #Covid 19 Call the Stopper Hotline 71863521335 or grab a free bottle (US only) just pay shipping EarthTea.Us." [Product name, PHOTO]: "COVID-19 SMOKING COUGH STOPPER" [Nov 3, 2020]

3. **USA-B4B00003146**: "To this day.. Earth Tea is the most effective Treatment against#COVID19 as Treatment and Prevention.. All NaturAl.. #TRYEARTHTEA Get well in 24-48 Hours..72 Hours MAX.." [Oct 9, 2020]

4. **USA-B4B00003148**: "Earth Tea the #1 #COVID19 fighter!!!!" [Oct 29, 2020]

5. **USA-B4B00003203:** "Covid19 Stopper Movement @b4bcorpusa – We would suggest to anyone out there facing #Covid19 issue. #TryEarthTea you do not have to be a #longhaulers Earth Tea can fight for you… EarthTea.US" [Nov 5, 2020]

6. **USA-B4B00003208**: "Covid19 Stopper Movement @b4bcorpusa – Earth Tea is the best treatment for #COVID19" [Oct 26, 2020]

7. **USA-B4B00003209**: "Covid19 Stopper Movement @b4bcorpusa – Today oct 29 mark 8 months since we Developed Earth Tea. After multiple adjustment to the formula we have mastered the body's response to #COVID19 we might be the only one to guarantee that officials are ignoring us or make it literally impossible to do clinical trials." [Oct 29, 2020]

8. **USA-B4B00003212**: "Covid19 Stopper Movement @b4bcorpusa – "We are the only one that guarantees our treatment works and works fast! Natural is completely different from Artificial. Earth Tea naturally attacks #Covid19 once it enters your system which sums up our volunteers experience that Earth Tea is like magic. blacks4blacks.com/ads-by-us" [Sep 2, 2020]. "We are 100% sure Earth Tea gets rid of #Covid19 #coronavirus and it does it Fast on big question now is can it be considered a vaccine. From one result it shows it can protect…". [Sep 1, 2020]

9. **USA-B4B00003214**: "Covid19 Stopper Movement @b4bcorpusa– #COVID19STOPPER one Bottle is all it takes..and you'll be back to normal fast. Quarantine? Bypass that with Earth Tea..100% fighters that fights virus because plants knows how to fight bacteria.. Kids safe, teen safe & adult safe. We are the #One #covid19" [Sep 15, 2020]

B. *From the B4B Twitter account:* ***Head Gone ® Earth Tea***

1. **USA-B4B00003226**: "I'm raising money for Earth Tea Extra Strength #2 Covid-19 clinical trial for 100 mixed patients including kids, critical and mild #Covid19 patients we are also looking to do our first trial against #Cancer to support us please donate here gofundme.com Covid-19 #2 Clinical Trials and Cancer #1 Trial, organized by Head Gone. Earth Tea Extra Strength has completed #1 Trial and results are Amazing… Head Gone needs your support for Covid-19 #2 Clinical Trials and Cancer #1 Trial"

2. **USA-B4B00003228**: "IF YOU'RE AGAINST COVID19 VACCINES STAND WITH EARTH TEA EXTRASTRENGTH. STAND FOR SOMETHING DON'T BE AN Obstructionist. STAND for common sense IF EARTH TEA WORKS IT SHOULD BE USED TO SAVE LIVES. Especially the fact it's 100% effective. Earthtea.US"

3. **USA-B4B00003241**: "When it comes to fighting Covid19 we have nothing more to say because our clinical trial report already shows we are 100% effective against getting rid of Covid19 and if that's not convincing enough for a system that relies on trials we don't know what else to say…"

4. **USA-B4B00003244**: "If your plan is to go Unvaccinated here's a must have natural immune booster. Earth Tea Extra Strength, its works extremely fast and it's 100% effective against Covid19 earthtea.US"

5. **USA-B4B00003266**: "#Facts. With proof from our clinical trial done in #india if you're tested positive for #Covid19 1-2 bottles will get you over Covid19 in 24-48 hrs… b4bearthteallc.com/earth-teat-extr…[image of the product]"

C. *From the B4B Twitter account:* ***B4B Earth Tea LLC***

1. **USA-B4B00003273**: "If you're battling covid give Earth Tea Extra Strength a shot for 2 days and you will be able to walk like it never happened. With 2 hours you will feel the changes start to happen after just half bottle. By the time you finish 1 bottle you will feel better then #2 is a charm." [Dec 30, 2021]

2. **USA-B4B00003274**: "Our clinical trial is still the most successful 100% we are the only one to guarantee 2 bottles will get you covid free in 24-48hrs. Protect your family add us to your Freezer and rest assured when it comes to Covid19. 2 bottles each family member is all it takes. We have been saying that since March 2020 and still saying the same thing today. Earth Tea Extra Strength can reverse and remove covid from the body. Earthtea.us" [Dec 20, 2021]

3. **USA-B4B00003275**: “To all #College campus you can solve covid issues by having students use Earth Tea Extra Strength… It can be drank as is mixed with juice but immediately change the course of Covid19 with just one mouth full. We can guarantee that.” [Dec 15, 2021]

4. **USA-B4B00003300**: “Please help us prevent 900,000 US death from #covid19. If you’re positive grab 2 bottles. . . . The moment you get your result or start feeling symptoms order 2 bottles right way EarthTea.Us our volunteers all reported success you will start feeling better with 2 Hrs” [Dec 23, 2021]

D. *From the B4B Facebook page:* ***B4BCorp***

1. **USA-B4B00003534**: B4BCorp is sharing a COVID-19 Update. [image]: “Awaiting Clinical Trials Earth Tea Extra Strength AGAINST Covid19” [April 22, 2021]

2. **USA-B4B00003541**: B4BCorp. “#Covid19… CAN’T Overpower the World’s first instant Immune Booster! If its not 1 bottle 2 or 3 and Covid19 Must Leave your system… Clinically Tested and did Excellent in our #1 Trial.. Www.earthtea.US Join the Movement!” [August 6, 2021]

3. **USA-B4B00003555**: B4BCorp. “Facts #Vaccines VS EARTHTEAEXTRASTRENGTH Vaccines trials shows preventing hospitalization is 85-96% while so far Earth Tea Extra Strength is 100% we have helped people who are vaccinated. No one who was positive and used Earth Tea went to hospital. Www. earthtea.US” [September 10, 2021]

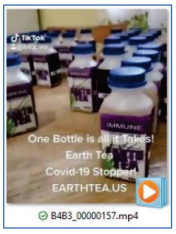
E. *From B4B Instagram post:* ***b4bearthteallc***

1. **USA-B4B00003639**: “Everyone in the US should have a case of Earth Tea at home stocked… so we can ease social distancing.. Right! No Mask Required… #covid19” [July 31, 2021]

2. **USA-B4B00003657**: “2 free bottles and then 1 year supply of Earth Tea Extra Strength for anyone who tested positive and willing to record using Earth Tea Extra Strength against #Covid19 Record and post random videos how you're feeling before and after trying Earth Tea Extra Strength text Positive to 718-635-2135 we can offer but the choice is yours” [Aug 30, 2021]

3. **USA-B4B00003660**: “… Grab 2 bottles keep it in your freezer in case Covid19 hits. Frozen will last for 1 year. DON’T DIE FROM COVID19. We are 100% sure we cans save you! Www.earthtea.US” [September 3, 2021]

F. *From B4B social media:* ***Videos***



1. **USA-B4B00003527**: “One Bottle is all it Takes! Covid-19 Stopper! EARTHTEA.US
Audio transcript 00:01 – 00:58 sec

"This is how ease to get rid of Covid-19. You could either drink it directly from the bottle or… drink it as were your favorite cup of tea. After this is finished do the same thing in the next 8 hours, that is the way you get rid of Covid-19"

2. **USA-B4B00003504**: Audio transcript 1:48 – 03:01 min
"My boss has Coronavirus and her son… I have no contracted Covid-19…. I just want to let other persons out there know there is something… to help you, you don't have to get sick, you don't have to die… I've been drinking for years, one bottle per month and I am no longer, I have no sugar, I have no diabetes anymore. It has been reversed because it was type 2…"

3. **USA-B4B00003564**: Audio transcript 00:07 – 01:10 min
"Ladies and gentlemen, for the past 15 months, we have been doing private trials against Covid-19 and other health issues… we can assure you that Earth Tea Extra Strength is safe for humans… we are expecting the clinical trials to reflect the 100% result that we have been seen all these 15 months… We hope to prove to you that Earth Tea Extra Strength… is the answer for Covid-19..."

G. *From B4B's* ***Website – https://b4bcorp.com***

1. **USA-B4B00003320**: "Our Clinical Trial was successful. So successful We are offering Money Back Guarantee against covid-19 if 2 bottles do not get you negative [for covid-19] you will get your money back! Test result and proof of consuming required" (p.7)

2. **USA-B4B00003332**: Earth Tea Extra Strength Clinical Trial #1 (p. 19-21)
"Earth Tea extra strength was developed while battling Covid-19. The idea was boost the immune system to overcome the Virus. It worked back in March of 2020 and still do today, as we try to share our good news we have been greeted with nothing but negative comments online…"

3. **USA-B4B-00000265 – USA-B4B-00003398**: Clinical Study Report Sponsored by Sinclair B4B Corp – Date 18 Sep 21

II. Other Types of Disease Claims

A. *From B4B's* ***Website – https://b4bcorp.com***

USA-B4B00003314: B4B Earth Tea LLC – [screenshot 9/16/2021]

1. "Earth Tea Extra Strength saves lives and ease pain" (p.3)

2. "Earth Tea Extra Strength Updates and Feedbacks" (p.13-14)
We are constantly in contact with everyone who tries Earth Tea Extra Strength because feedbacks help us get closer to perfection... As people with different conditions try it and gives feedbacks we can advise you more as far as what it can help with. Keep in mind our ingredients is simple with nothing unknown to scientists or officials everything in our product can be bought at your local grocery store.

insomnia - 2-3 oz hot will let you rest well
tachycardia - irregular heartbeat seems to normalize
joint pain - numerous reports about pain relief
Lupus - reports of less flares after trying Earth Tea But due to the complexity of lupus we need more feedbacks and possibly a clinical trial done
asthma - less use of pump after Earth Tea use but we need more feedbacks
coughing - coughing almost instantly stopped depending on severity it may require 1 to 2 bottles
fever - mysteriously fever goes away within minutes to hours you will feel your body temperature normalize
diabetes no reports of negative reactions from anyone with diabetes most people report feeling ease from issues they normally have from diabetes
heart surgery- no reports of any issues or negative reaction from people who have done major heart surgery. Many reported having more energy and been able to do more
kidney transplant- no reported issue from people who had kidney transplant done and tried Earth Tea
Stomach issues - gastroenteritis relief starts in minutes. Earth Tea Extra Strength instantly start push bad stuff out your system
Kids - the youngest so far reported is 3 yrs old who tried it against covid19. No issues reported…
Vaccinated people No reported issues for those who are already Vaccinated. We had people who tested positive for Covid19 after been Vaccinated use Earth Tea Extra Strength and theres no issues.

3. **USA-B4B00000650**: "Stage 4 Colon Cancer Success!" [10/17/2022]
   May 31, 2D22 Feedback received and verified.
   "We received updates from our # 1 volunteer who tried 4 Bottles of our Immune drink Earth Tea Extra Strength for 7 Days against stage 4 Colon Cancer. His Blood work now shows Complete Remission which means no cancer cell present in his blood. That's Amazing New!! We appreciate his trust and faith in our 100% natural product."

B. *From Twitter account* B4B Earth Tea LLC @ b4bbearthteallc

1. **USA-B4B00004970**: Twitter Tread
   B4B Earth Tea LLC @b4bearthteallc, Replying to @b4bearthteallc
   "Earth Tea because your stomach is feeling funny and after drink 2 bottles your prostate went back to normal, your pressure numbers went down, a pain in your side suddenly gone. There's so many stories from the World's first Instant immune booster. Scientists dismissed us so many Times . . . ." [Mar 8, 2022]

2. **USA-B4B00001569**: Twitter Tread
   "Oct 31 she was Told the Cancer is so bad they can't help her .. They gave her 30 days ... We entered the battle Nov 26th 3 bottles at her side for now.. Better late than never ... attempting to remove the expiration date. ..lets Pray for a #Cancerworrior # Cancer" [Nov 28, 2022]

3. **USA-B4B00003224**: Twitter post
   "If you're battling #Cancer before you start chemotherapy you can try Earth Tea Extra Strength while waiting and hope you can avoid it by time the Date comes! 1/2 gallon and 5 days may reverse it and change your life earth tea.US" [Oct 26, 2021]

4. **USA-B4B00001649**: B4B Earth Tea @EarthTeaOutlet
   Retweet if you know someone with #prostate issues. Send to a Male friend or Family member. one Love!! B48 Earth Tea @EarthTeaOutlet - Sep 8 Prostate awareness by B4B Earth Tea. my dad died from Prostate Cancer wish he had this Option, To all men out there our Natural Immune Drink is doing well you can always 'Try it' before using a Catheter #prostate #ProstateCancer" [Sep 10, 2022]

C. *B4B Facebook posts at* www.facebook.com/b4bcorpUSA

1. **USA-B4B00006464**: From www.facebook.com/b4bearthtea 8/14/2022
   "The more Success we have the More Awareness ... Our Success with Colon Cancer opens the Door to save people battling Colon Cancer.
   Earth Tea Extra Strength + Your immune system can overcome Colon Cancer
   Available soon globally at www.b4bearthtea.com
   #Coloncancer #colonissues #colonawareness #colon"

2. **USA-B4B00003532**: From Facebook page B4Bcorp [screenshot from 10/8/2021]
   "Earth Tea Extra Strength the world's most powerful natural supplement. After we tackle #Covid19 with our Clinical Trials that should begin anytime now, we would like to try Earth Tea Extra Strength Against every known illness known to mankind. Whether It's #Arthritis, #asthma, #insomnia, #overdose, #cancer, #HIV, #lungs issues, #kidneystones, etc. Earth Tea Extra Strength helps your body fight…" [April 15, 2021]

D. *From B4B Instagram posts:* ***b4bearthteallc***

1. **USA-B4B00003221**: Instagram post
   "b4bearthteallc Know anyone with HIV or Cancer? We would like to try 1/2 gallon of Earth Tea Extra Strength against #HIV AND #CANCER 2 cups per day for 5 days! #EARTH TEA Www.earthtea.US" [October 8, 2022]

ATTACHMENT 2

2a - PubMed/MEDLINE search results:

PubMed Advanced Search Builder

PubMed®

Add terms to the query box

All Fields

Enter a search term

ADD Show Index

Query box

Enter / edit your search query here

Add to History

Your search was processed without automatic term mapping because it retrieved zero results.

History and Search Details

Search	Actions	Details	Query	Results	Time
#10	•••		Search: **Earth Tea Extra Strength**	0	16:12:47
#9	•••		Search: **Earth Tea Extra Strength - Schema: all**	0	16:12:47
#8	•••		Search: **'Earth Tea'**	200	16:09:50
#7	•••		Search: **Earth Tea**	200	16:09:34
#6	•••		Search: **B4B Earth Tea**	0	16:09:18
#5	•••		Search: **B4B Earth Tea - Schema: all**	0	16:09:18
#4	•••		Search: **B4B Earth Tea LLC**	0	16:08:56
#3	•••		Search: **B4B Earth Tea LLC - Schema: all**	0	16:08:56
#2	•••		Search: **'B4B Corporation'**	1	16:08:00
#1	•••		Search: **B4B Corporation**	1	16:07:44

Showing 1 to 10 of 10 entries

FOLLOW NCBI

Screenshot of seach query #1 and #2 - Abstract

Forensic Sci Int Genet. 2019 Nov;43:102143. doi: 10.1016/j.fsigen.2019.102143. Epub 2019 Aug 13.

Resolving mitochondrial haplogroups B2 and B4 with next-generation mitogenome sequencing to distinguish Native American from Asian haplotypes

Melody R Wood [1], Kimberly Sturk-Andreaggi [2], Joseph D Ring [2], Nicole Huber [3], Martin Bodner [3], Michael H Crawford [1], Walther Parson [4], Charla Marshall [5]

Affiliations

PMID: 31473588 DOI: 10.1016/j.fsigen.2019.102143

Abstract

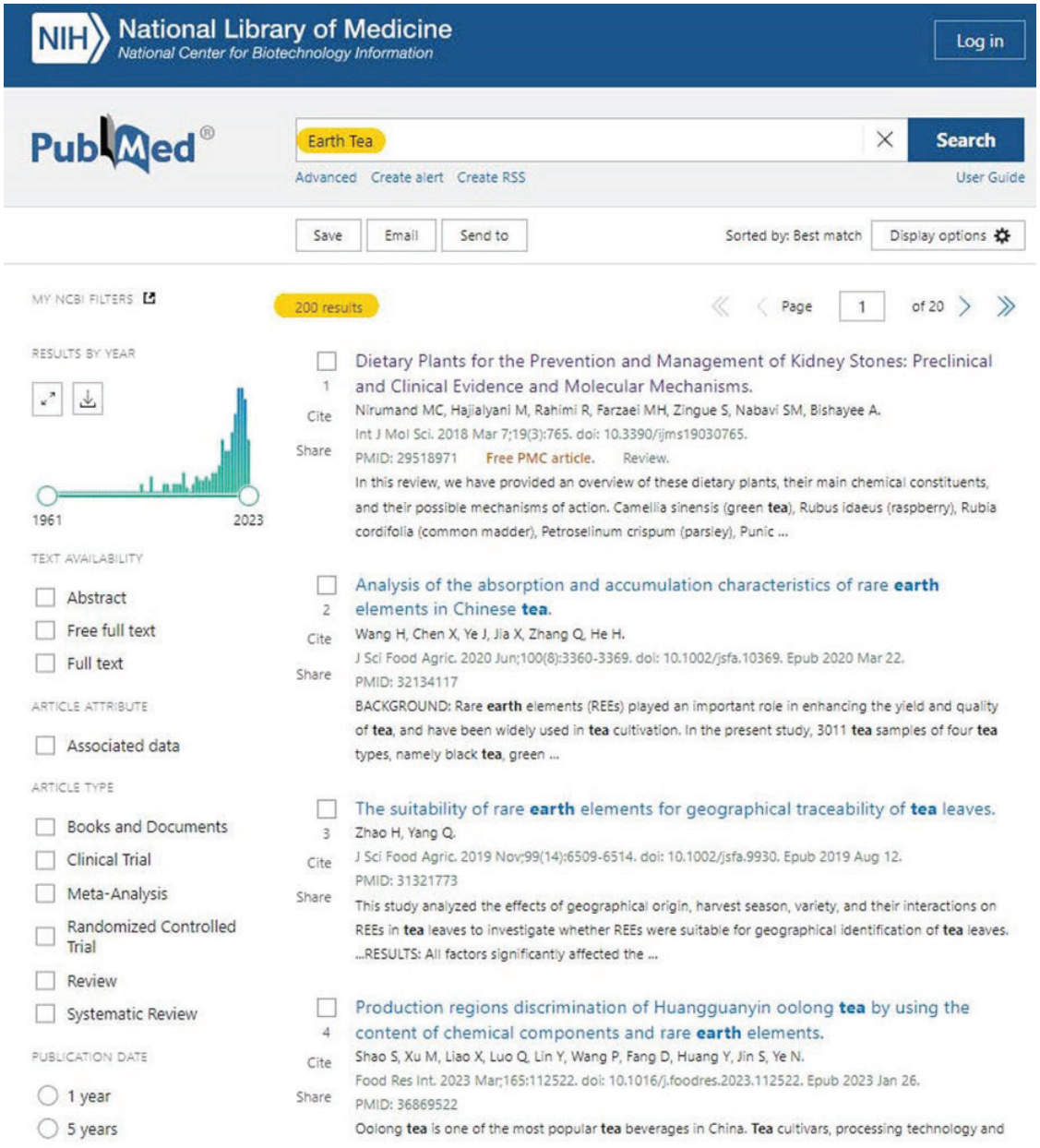
Mitochondrial haplogroup information can be useful in forensic contexts that rely primarily on mitochondrial DNA (mtDNA) testing, which often involve limited or degraded DNA. Due to the phylogeographic patterning of mtDNA in human populations, mitochondrial haplogroups are indicative of maternal ancestry (as mtDNA is a maternally inherited marker). In certain circumstances, maternal ancestry inferred from mitochondrial haplogrouping could be beneficial to forensic investigations. For example, ancestry information could assist in the identification of unknown service members from past conflicts, such as the World War II Battle of Tarawa involving American and Japanese forces. In this context, it could be useful to distinguish Native American mtDNA from Asian mtDNA to bolster the anthropological and circumstantial evidence leading to an identification or foreign national determination. Although most of the founding Native American haplogroups contain diagnostic variants in the mitochondrial control region (CR), haplogroup B2 does not, and this makes it more difficult to distinguish B2 from the parental B4 and closely related B4b haplogroups found in Asia. In this paper, the amount of mtDNA information required to distinguish Native American haplotypes from Asian haplotypes within haplogroup B was examined. Fifty-six samples belonging to subtypes of B2 and B4 were sequenced for the entire mitogenome. Haplogroups were estimated from three ranges of mitochondrial DNA (HV1 and 2, CR, and full mitogenome). Half of the samples could not be precisely haplogrouped without full mitogenome data, although enough variants were often provided to make an accurate B2 versus B4 distinction. Native American B2 haplotypes were distinguishable using CR data alone in 82% of samples, though the remaining samples required full mitogenome data for haplogroup B2 designation. The use of full mitogenome data consistently enables accurate haplogroup determination, and opens the possibility for gaining information on maternal ancestry.

Keywords: Ancestry; Haplogroup B; Mitochondrial genome; Next-generation sequencing; Phylogenetics.

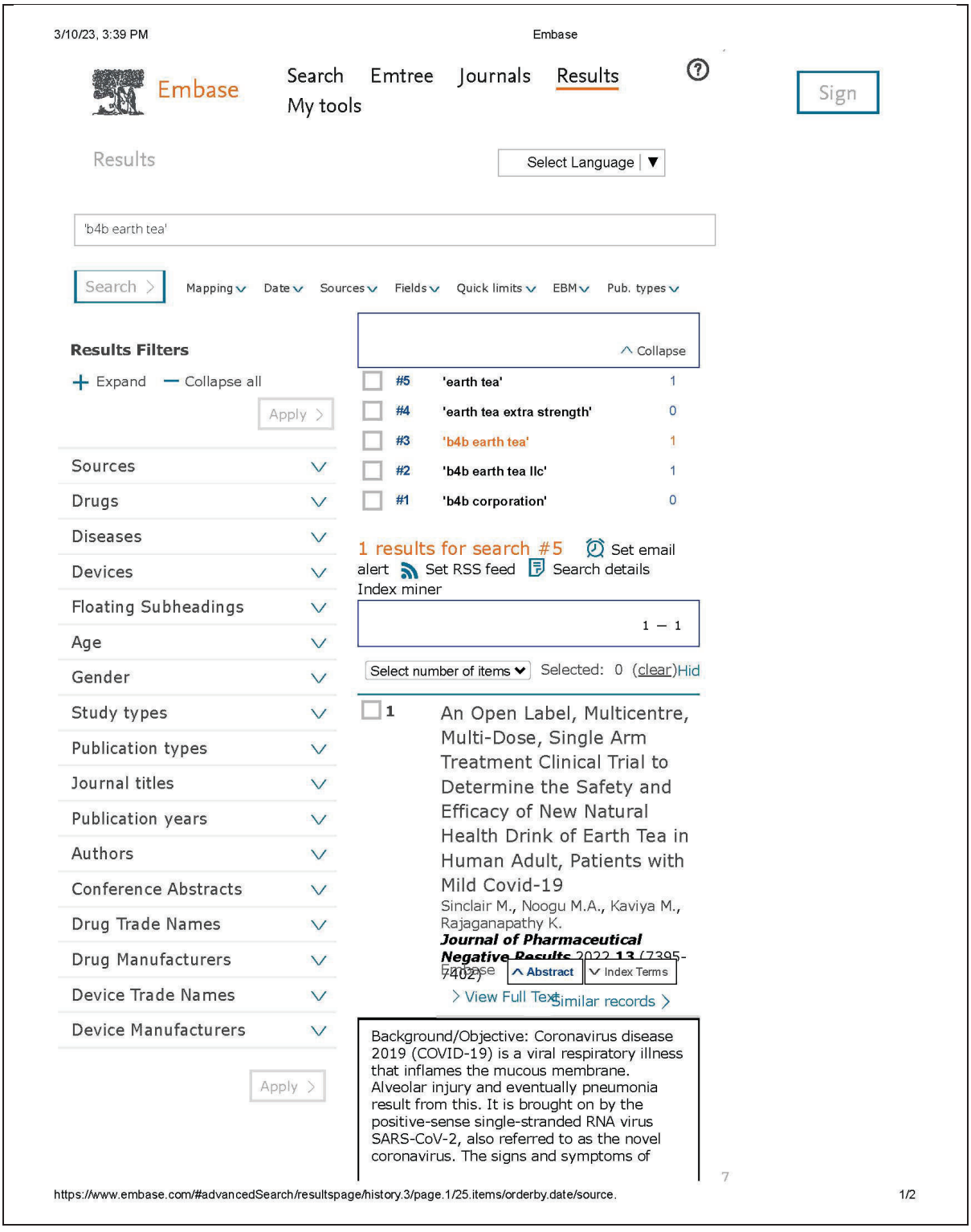
Related information

MedGen
Nucleotide
Nucleotide
PopSet
Protein

Screenshot of seach query #7 and #8 – Page 1 of 20



2b - EMBASE search results:



Copy of the Defendants' published in the "Journal of Pharmaceutical Negative Results | Volume 13 | Special Issue 9 | 2022"

Original Article

An Open Label, Multicentre, Multi-Dose, Single Arm Treatment Clinical Trial To Determine The Safety And Efficacy Of New Natural Health Drink Of Earth Tea In Human Adult, Patients With Mild Covid-19

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DOI: 10.47750/pnr.2022.13.S09.866

Abstract

Background/Objective: Coronavirus disease 2019 (COVID-19) is a viral respiratory illness that inflames the mucous membrane. Alveolar injury and eventually pneumonia result from this. It is brought on by the positive-sense single-stranded RNA virus SARS-CoV-2, also referred to as the novel coronavirus. The signs and symptoms of COVID-19 include fever, dry cough, exhaustion, sore throat, diarrhoea, headache, conjunctivitis, nasal congestion, body aches and pains, fatigue, loss of taste and smell, a skin rash, and discoloration of the fingers or toes. The main focus of research has been on current antiviral medications as prospective COVID-19 treatments. Hence, the present work was focused for clinical studies for the determinations of SARS-COV-2 (COVID-19) safety and efficacy of the new natural health drink of "Earth Tea". The product of "Earth Tea" Manufactured By Martin Sinclair B4B Corp,40, Remsen Ave, Brooklyn, NY 11212 ,United States.

Methods: An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19 was the main goal of the study. To assess the safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult patients with COVID-19 infections.

Results: In the analysis, patients showed a significant reduction in clinical cure and micro biologically cure analysis on Day 02 of evaluation visit. Moreover, significant reduction in the RT-PCR report noted on Day-02 and there were no adverse events reported during course of the study. Therefore, there were no Serious adverse events or deaths reported in this study.

Conclusion: Based on these results obtained in the study, the product is an Earth Tea was found to have a significant efficacy and also a safe product.

Key Words: Earth tea, COVID-19, SARS-COV-2, Clinical trial, Safety and efficacy and Multicenter-Multi-Dose-Single Arm-Treatment Clinical Trial.

Introductions:

Coronavirus disease 2019 (COVID-19) is a viral respiratory illness that inflames the mucous membrane. Alveolar injury and eventually pneumonia result from this. It is brought on by the positive-sense single-stranded RNA virus SARS-CoV-2, also referred to as the novel coronavirus[1]. In the past, coronaviruses were linked to the Middle East respiratory syndrome (MERS) and the severe acute respiratory syndrome (SARS) (MERS) [2]. The signs and symptoms of COVID-19 include fever, dry cough, exhaustion, sore throat, diarrhoea, headache, conjunctivitis, nasal congestion, body aches and pains, fatigue, loss of taste and smell, a skin rash, and discoloration of the fingers or toes [3]. The main focus of research has been on current antiviral medications as prospective COVID-19 treatments. such as Ritonavir, Favipiravir, Lopinavir, and Remdesivir. Some antimalarial medications, including chloroquine and hydroxychloroquine, are utilised in the treatment of COVID-19. Another broad-spectrum antiviral medication used to treat the coronavirus condition is ribavirin. Ivermectin is being investigated as a COVID-19 therapy. Nutrition is important for health, especially when the immune system may need to defend itself. Consuming fresh fruits and vegetables aids in disease prevention and immune maintenance [4].

Hence, the present work was focused for clinical studies for the determinations of SARS-COV-2 (COVID-19) safety and efficacy of the new health drink of “Earth Tea”. The product of “Earth Tea” Manufactured by Martin Sinclair B4B Corp,40, Remsen Ave, Brooklyn, NY 11212, United States. Earth Tea is made of a combination of natural vegetable, Aloe Vera and Honey known to help to boosts our immune system. Earth Tea is 1-4 servings per bottle 16oz total with recommended servings of 8oz each, but 4oz can also be used. Earth Tea Extra Strength may be used to continuously boost our immune system, which may be used as 1 bottle every two weeks or at least one bottle per month to assist the immune system. Earth Tea might help with other issues where more than one bottle might be required per month in that case, 2 bottles max within 48 hours can be consumed with 8oz per serving every 8-10 hours. Earth Tea is all natural and might be hard to swallow because of the taste, it may be combined with juice and it will still be effective. Which mainly focused to increase the immunity level in human and helps to maintain the antioxidant levels which help to reduce the symptoms of COVID-19 infection. It is also helps in restoration of smell and taste.

Hence. An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19 [5] was the main goal of the study. To assess the safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult patients with COVID- 19 infections.

Materials and Methods:

The study protocol with the number EART-001-21 was created on May 1 and received IEC clearance on July 5 of that same year. 20 Mild COVID- 19 patients in all were screened and participated in the trial. Prior to drug administration and up until the day of visit completion, enrolled participants were present in the clinical institution. The product being studied is called "Earth Tea," and it is made by Martin Sinclair B4B Corp. The 08 ounces of cold tea were taken orally in the morning, and 08 ounces of hot tea were taken orally exactly 12 hours later, two hours before bed. A study was focused for An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19, to assess the safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult patients with COVID-19 infections.

The study was conducted as per the pertinent requirements of the Ethical guidelines for biomedical research on human participants, ICMR (2017), ICH (Step 5)[6] 'Guidance on Good Clinical Practice’ [7], 'Good Laboratory Practice' [8-9], ‘Good Clinical Practices for Clinical Research in India’ Guidelines, Good Clinical Laboratory Practice (GCLP) [10], Declaration of Helsinki (Fortaleza, October 2013), New Drugs and Clinical Trials Rules 2019 G.S.R. 227(E) dated 19 Mar 2019 and applicable regulatory requirements.

Diagnosis and main criteria for inclusion: are the patients meet with all following criteria has considered for enrollment in the study: 1.Voluntarily participating in the clinical study; fully understanding and being fully informed of the study and having signed the Informed Consent Form (ICF); willingness and capability to complete all the study procedures. 2.Human adult patient with in the age limit of 18-75 years (both inclusive) were enrolled.

3. Patients who have evidence of laboratory confirmed infection with SARS-CoV-2 by positive RT-PCR were enrolled for this study (within 48 hours prior to randomization) [11-12]. 4.Patients who have uncomplicated respiratory tract viral infection were enrolled in this study. 5. Who have the evidence of controlled diabetic patients with HbA1C limit< 7.0 were enrolled in this study 6. Hypertension Patients up till Hypertension Stage 2 were included in the study (Systolic blood pressure at least 140mm Hg and Diastolic blood pressure at least 90 mm Hg) 7. The patients who have a time interval between symptoms onset and randomization to no more than 7 days were included in the study. 8.Pyrexia (axillary > 98.6°F or frontal >99.5°F); or/and any of the following symptoms having patients were included in the study: Cough, Sore throat, Headache, Nasal congestion, Body aches and pains, Fatigue, Patients who have the evidence with Loss of smell and Taste were included in the study and Pregnant or lactating women were not included in the study. The study experiment is mainly focused for RT-PCR test. The Investigational (Test) products "Earth Tea" were stored in refrigerator as per product label instructions received from the sponsor and The study was conducted at Primary Health Care Centre, Kunigal, Karnataka India.

Statistical Analysis:

The statistical evaluation were performed by using Chi square test. Statistical analysis were performed using the latest version of SAS® system software (SAS Institute Inc., USA).

Results and Discussion:

Coronavirus disease 2019 (COVID-19) is a viral respiratory disease and causes inflammation of the mucosal membrane. This leads to alveolar damage and eventually pneumonia. It is caused by SARS-CoV-2, commonly known as novel coronavirus, a positive-sense single-stranded RNA virus. Earlier, coronaviruses have been reported to cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). Symptoms of COVID-19 like Fever, Dry cough, Tiredness, Sore throat, Diarrhea, Headache, Conjunctivitis, Nasal congestion, Body aches and pains, Fatigue, Loss of smell and taste, a rash on skin or discoloration of fingers or toes.

The present work was focused for clinical studies for the determinations of SARS-COV-2 (COVID-19) safety and efficacy of the new product "Earth Tea". Earth Tea is made of a combination of natural vegetable, Aloe Vera and Honey known to help to boosts our immune system. Earth Tea is 1-4 servings per bottle 16oz total with recommended servings of 8oz each, but 4oz can also be used. Earth Tea Extra Strength may be used to continuously boost our immune system, which may be used as 1 bottle every two weeks or at least one bottle per month to assist the immune system. Earth Tea might help with other issues where more than one bottle might be required per month in that case, 2 bottles max within 48 hours can be consumed with 8oz per serving every 8-10 hours. Earth Tea is all natural and might be hard to swallow because of the taste, it may be combined with juice and it will still be effective. Which mainly focused to increase the immunity level in human and helps to maintain the antioxidant levels which help to reduce the symptoms of COVID-19 infection. It is also helps in restoration of smell and taste.

Hence. An Open Label, Multicenter, Multi-Dose, Single Arm Treatment Clinical Trial in Human Adult Patients with Mild COVID-19 was the main goal of the study. To assess the safety and effectiveness of "Earth Tea" for COVID-19 as well as the safety and tolerability of a multi-dose given to human adult of patients with COVID-19 infections and approximately 15 patients were planned to be treated and analyzed for up to 10 days.

The study was divided into 3 Visits for a total of study **Shown Figure-1:** 1). Study Enrollment Visit (Day 00) 2). On therapy visit (Day 01) and 3). Evaluation Visit (Day 02). The duration of this study was 10 days (The study treatment duration was 04 to 05 days for each patient **shown figure-2**) from the day of check-in of first patient (05 Jul 21) to (14 Jul 21). The patients were given in the morning 08 Oz of cold tea will be administered orally and 08 Oz of Hot tea were administered after12 hours exactly two hours before bed.

Test product (T) in the first visit the dose was administered twice for day 01 in the clinical facility under the supervision of Investigators.

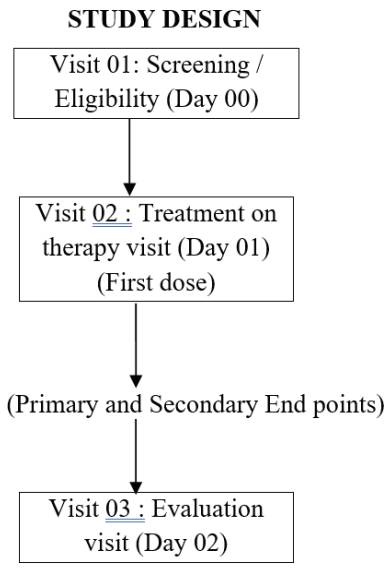


Figure-1: Shown The clinical trial study design

In the analysis, patients showed a significant result in Clinical cure and Microbiological cure efficacy analysis on Day 02 (End of Study). Demographic data, medical and medication history, physical examination and RT-PCR were did prior to study enrolment. The Documentation of CT-Chest for available patients were collected before to study enrolment. The Informed consent (ICD) were read and signed prior to the study specific procedures before enrollment of all the patients. And additionally, urine pregnancy test was performed at each visit of the study. On the day of enrollment visit (Day 00) following list of procedures were done to the all patients.

I. Obtaining the ICD
II. Inclusion and Exclusion criteria compliance has verified
III. Medical and Medical history was collected
IV. RT-PCR was done
V. Physical examination and vitals performed as per the protocol
VI. Safety evaluation and Monitoring for AE were done.

On day of therapy visit (Day 01) dosing was done as per the protocol. Safety evaluation and Monitoring for AE were done for all patients. On the day of evaluation visit (Day 01) following list of procedures was did as per the protocol.

I. RT-PCR was done
II. vitals performed as per the protocol
III. Safety evaluation and Monitoring for AE were done
IV. Efficacy evaluation was done as per the protocol

All the procedures and tests has been done in the clinical facility under the supervision of the Investigator on dosing day (Day 00) to Evaluation visit (Day 02) and AE were monitored. The quality of life was assessed by the questionnaires.

Therapeutic efficacy was determined based on the cure and Microbiological cure efficacy analysis on Day 02 (End of Study) and Microbiological cure efficacy analysis on Day 02. The Clinical cure was maintained up to 48 hours, Patients respond or not to treatment, based on the efficacy evaluation on the Day 02 for clinical cure and microbiological cure. After Day 02 Patient was continued with Standard Treatment based on the discretion of Investigator. The evaluation of product tolerance and nature of side effects also were summarized. Totally 15

generally human adult, patients with mild COVID 19 were enrolled and completed the study.

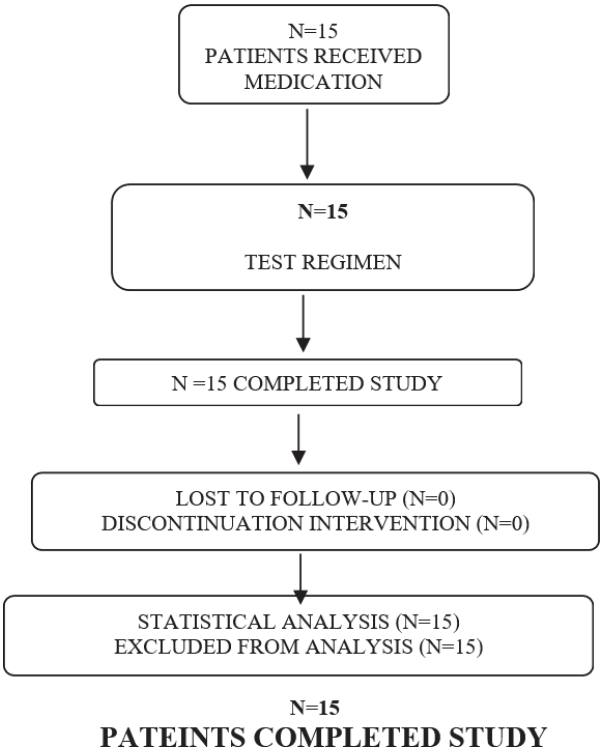


Figure-2: Patients Enrollment and Summaries

The product is a Earth Tea Manufactured By Martin Sinclair B4B Corp, 40, Remsen Ave, Brooklyn, NY 11212, United States and there is no deviation in this study. The Population analysis set included all enrolled patients who were exposed the treatment. A total of 15 patients were enrolled into the study and their mean age was 43 years respectively and All patients included in the study were Asian were **shown on Table-1**. The test investigational drug a product was administered to the patients at time of dosing and there was no deviation in drug dosing.

Table 1: Summarized Demographic Profile of Patients

Demographic details of patients who were participated and completed in the study (N=40)					
Parameter	**Mean**	**SD**	**Min**	**Max**	**CV%**
Age (years)	43	11.45	23.00	64.00	26.41

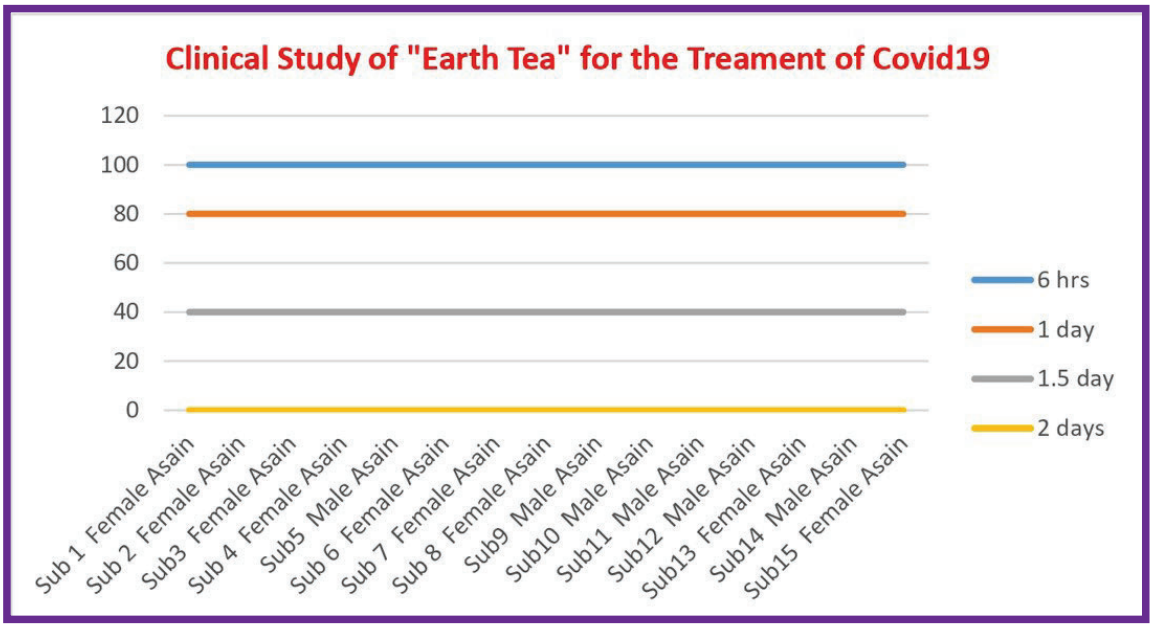
In the patients showed a significant result in their respond to treatment based on the efficacy evaluation on Day 02. The Data were reported as clinical cure and microbiological cure efficacy evaluation on Day 02. The lineal cure has maintained up to 48 hours. Safety data was summarized and tabulated and depending on the number of observations, a decision was made whether to test the significance of any values. The data from 15 Patients who completed the study received test product were considered to perform the Efficacy analysis and its applicable for multicenter study. Hence, the data of 15 patients were considered to perform statistical analysis. The Individual RT-PCR report for all patients were generated.

In efficacy study, the data from 15 Patients who received the Investigational drug and completed the study were

considered to perform the Statistical analysis by using the latest version of SAS® system software (SAS Institute Inc., USA). In the analysis, patients showed a significant reduction in clinical cure and micro biologically cure analysis on Day 02 of evaluation visit. Moreover, significant reduction in the RT-PCR report noted on Day-02. Hence, we can conclude that drug is showing very good results on Day-02 of evaluation visit. There were no adverse events reported during course of the study. Therefore, there were no Serious adverse events or deaths reported in this study.

During the course of study at every visit, blood Pressure, radial pulse rate, oral temperature and wellbeing status were enquired and recorded. RT-PCR were done on the day of before enrollment. Available CT-Chest documentation was collected. Therefore, were no variations on obtained.

Based on these results obtained in the study, the product is an Earth Tea Manufactured by Martin Sinclair B4B Corp, 40, Remsen Ave, Brooklyn, NY 11212, United States was found to have a significant efficacy and also a safe product **Shown Graph-1 and Table-2.**



Graph-1: Shown the RT-PCR Results of Each Human Subjects: X-axis Indicating The Subjects of 15 Asian Human Voluntaries, Y-axis Indicating the RT-PCR Effect of Each Subjects based on 6hrs, 1-Day, 1.5-Day and 2-Days (48 Hrs). The Earth Tea having the Significant Efficay of COVID-19 (The Nagative results shown after or before 48 Hrs).

Table 2: Individual demographic data of all patients (N=15) enrolled in the study

Subject No	Age (yrs)	Gender	Race	Smoking status	Results
1	34	Female	Asian	Non-smoker	Safe and significant Efficacy
2	29	Female	Asian	Non-smoker	Safe and significant Efficacy
3	30	Female	Asian	Non-smoker	Safe and significant Efficacy

4	30	Female	Asian	Non-smoker	Safe and significant Efficacy
5	21	Male	Asian	Non-smoker	Safe and significant Efficacy

Subject No	Age (yrs)	Gender	Race	Smoking status	Results
6	60	Female	Asian	Non-smoker	Safe and significant Efficacy
7	55	Female	Asian	Non-smoker	Safe and significant Efficacy
8	38	Female	Asian	Non-smoker	Safe and significant Efficacy
9	27	Male	Asian	Non-smoker	Safe and significant Efficacy
10	25	Male	Asian	Non-smoker	Safe and significant Efficacy
11	32	Male	Asian	Non-smoker	Safe and significant Efficacy
12	32	Male	Asian	Non-smoker	Safe and significant Efficacy
13	28	Female	Asian	Non-smoker	Safe and significant Efficacy
14	33	Male	Asian	Non-smoker	Safe and significant Efficacy
15	35	Female	Asian	Non-smoker	Safe and significant Efficacy

Conclusion:

The findings of this study clearly suggest that the Earth Tea manufactured by Martin Sinclair B4B Corp at 40 Remsen Avenue, Brooklyn, New York 11212, USA, is effective in reducing COVID-19 levels significantly when patients report their RT-PCR results. The analysis showing that the product is statistically effective. According to the data, patients displayed a substantial difference between their enrollment visit on day one and their evaluation visit on day two. As a result, we can say that the medicine is producing excellent outcomes as of the second day of the evaluation visit. All patients had a very positive experience with the medication of the product. Additionally, the patients weren't very concerned about any potential side effects, dosage restrictions, or their regular lives. Since none of the adverse events occurrences were determined to be caused by the study medicine of the product, Hence, the product's safety was amply demonstrated.

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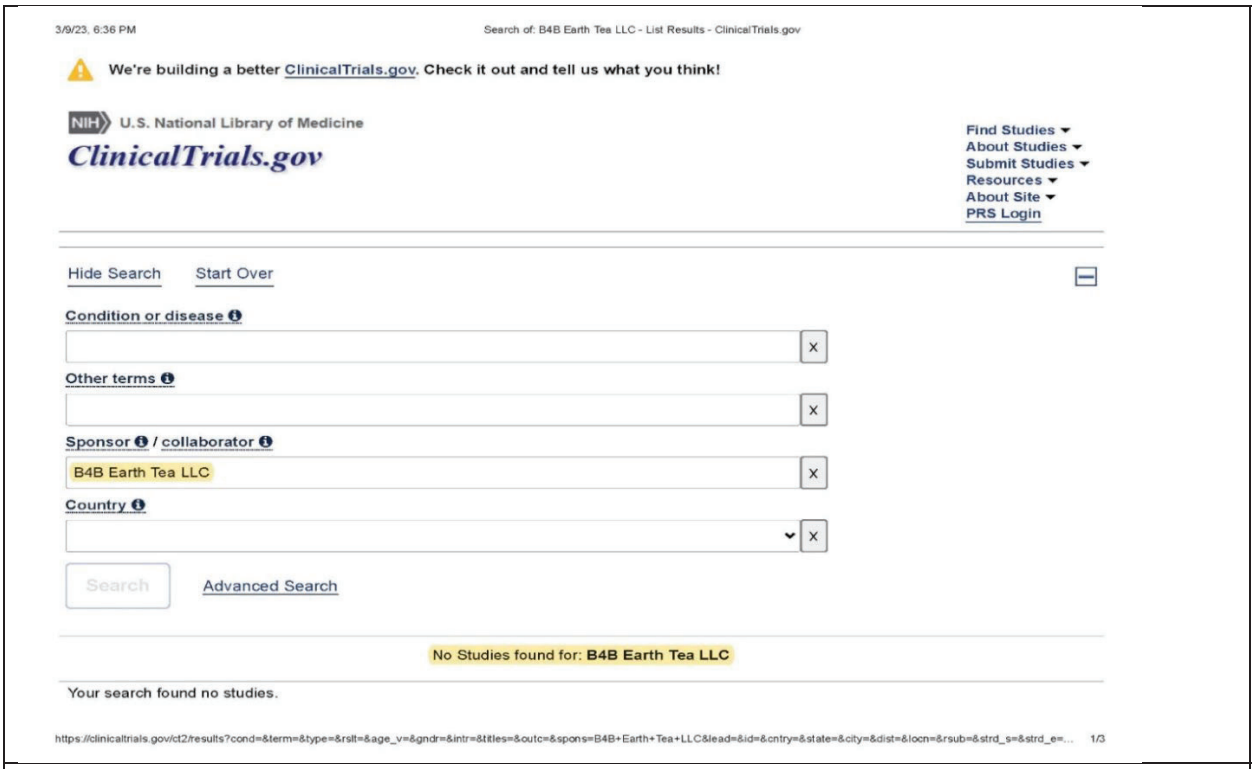
12. Diagnostic detection of 2019-nCoV by real-time RT-PCR., Berlin, Jan 17th, 2020., https://www.who.int/docs/default- source/coronaviruse/protocol-v2-1.pdf.

2c - ClinicalTrials.gov search results:



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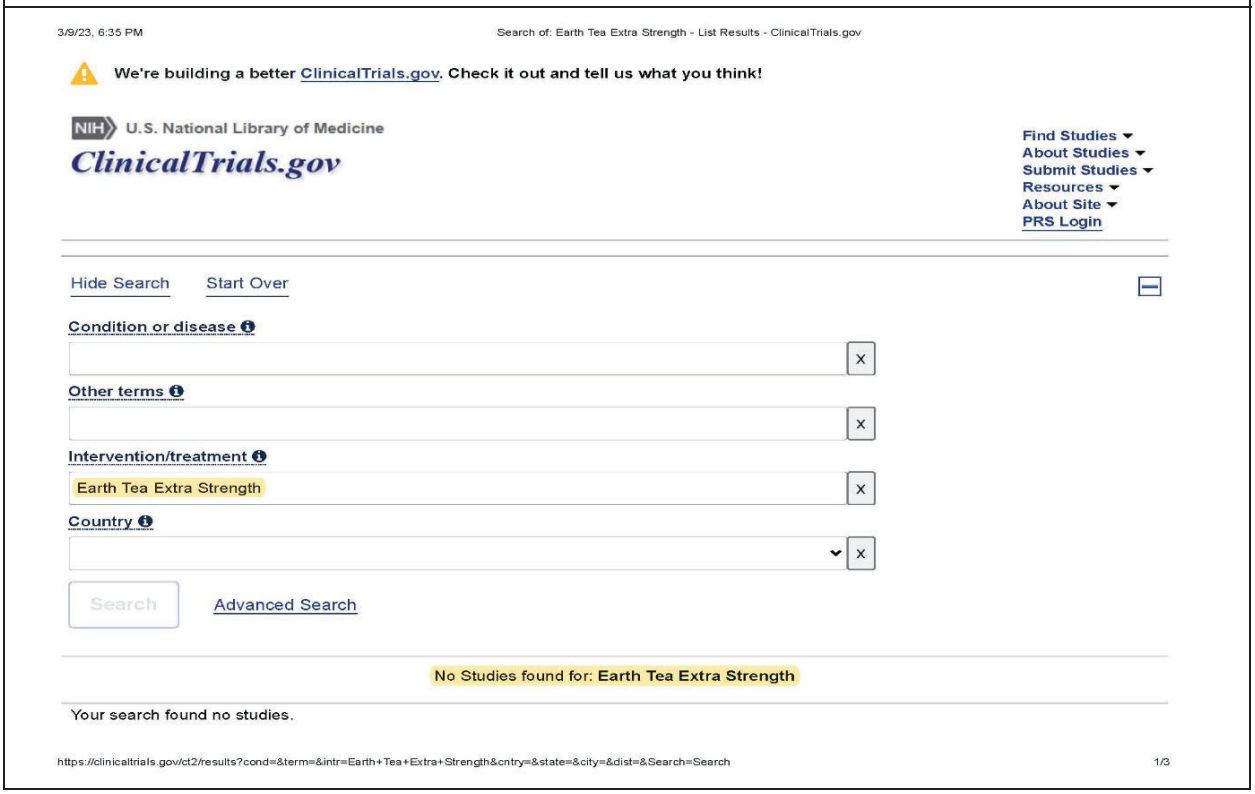

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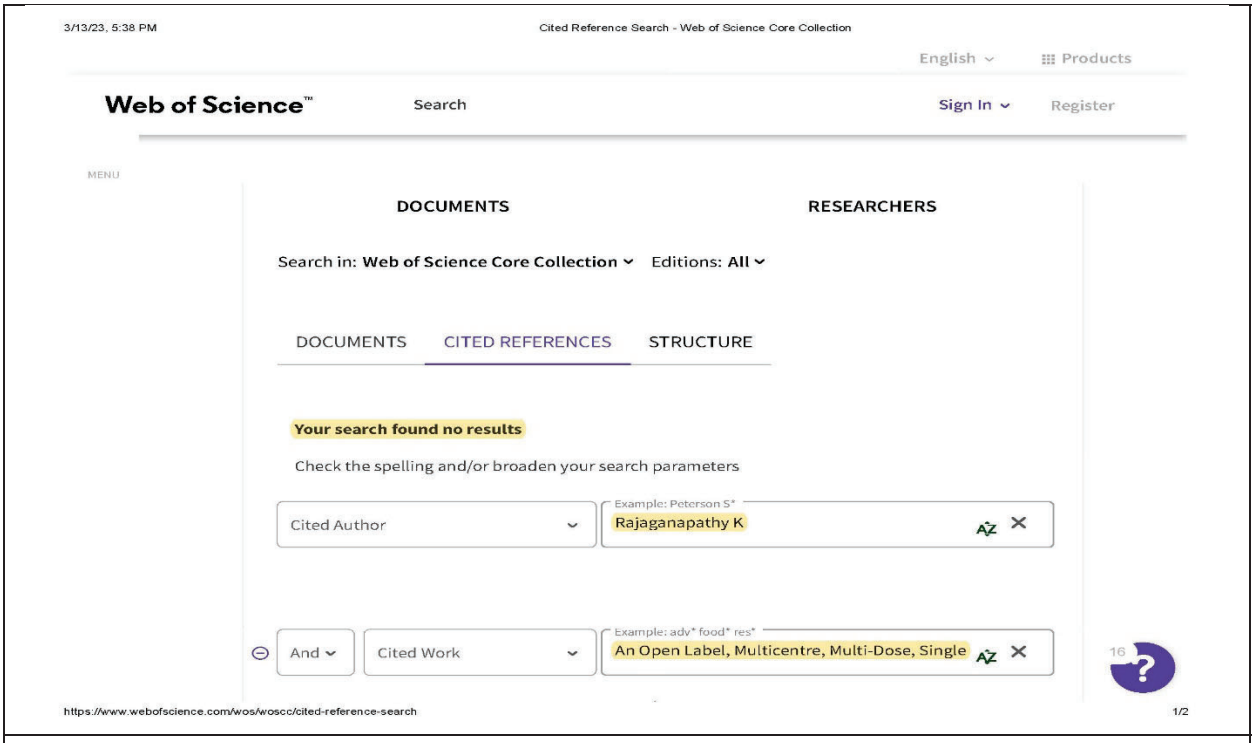

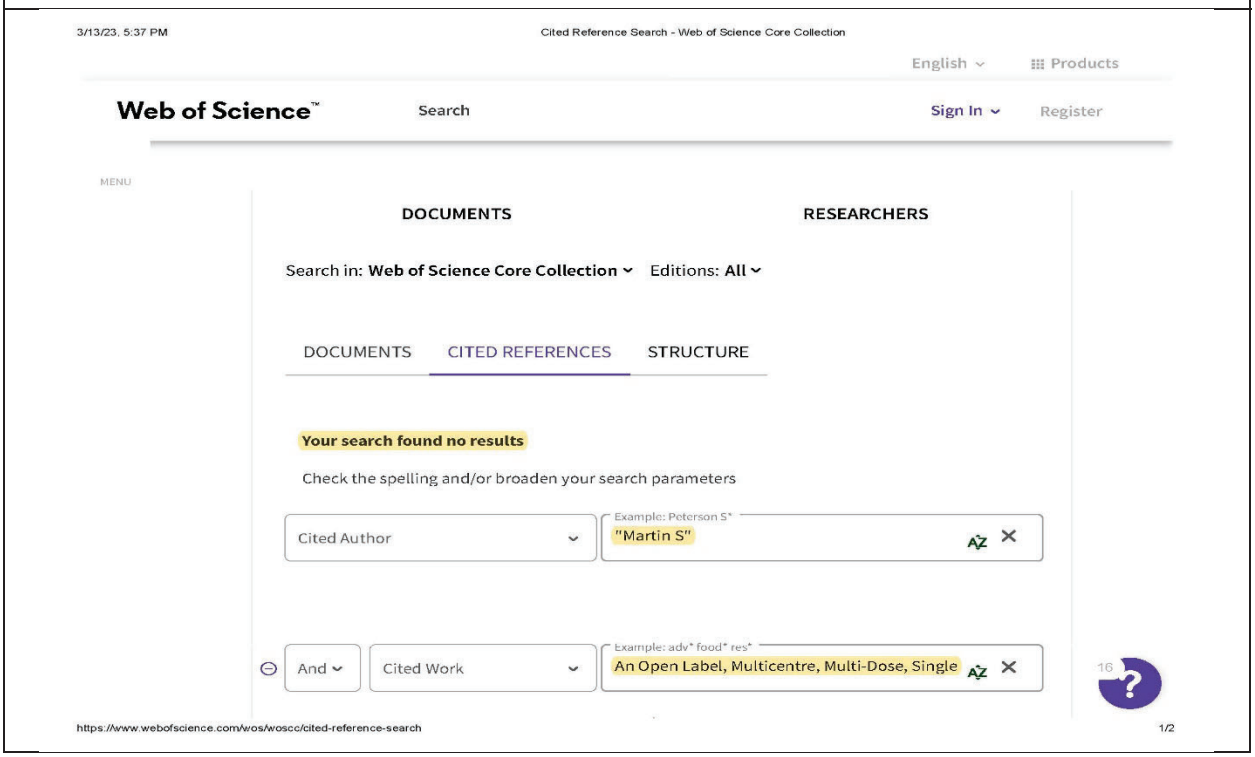

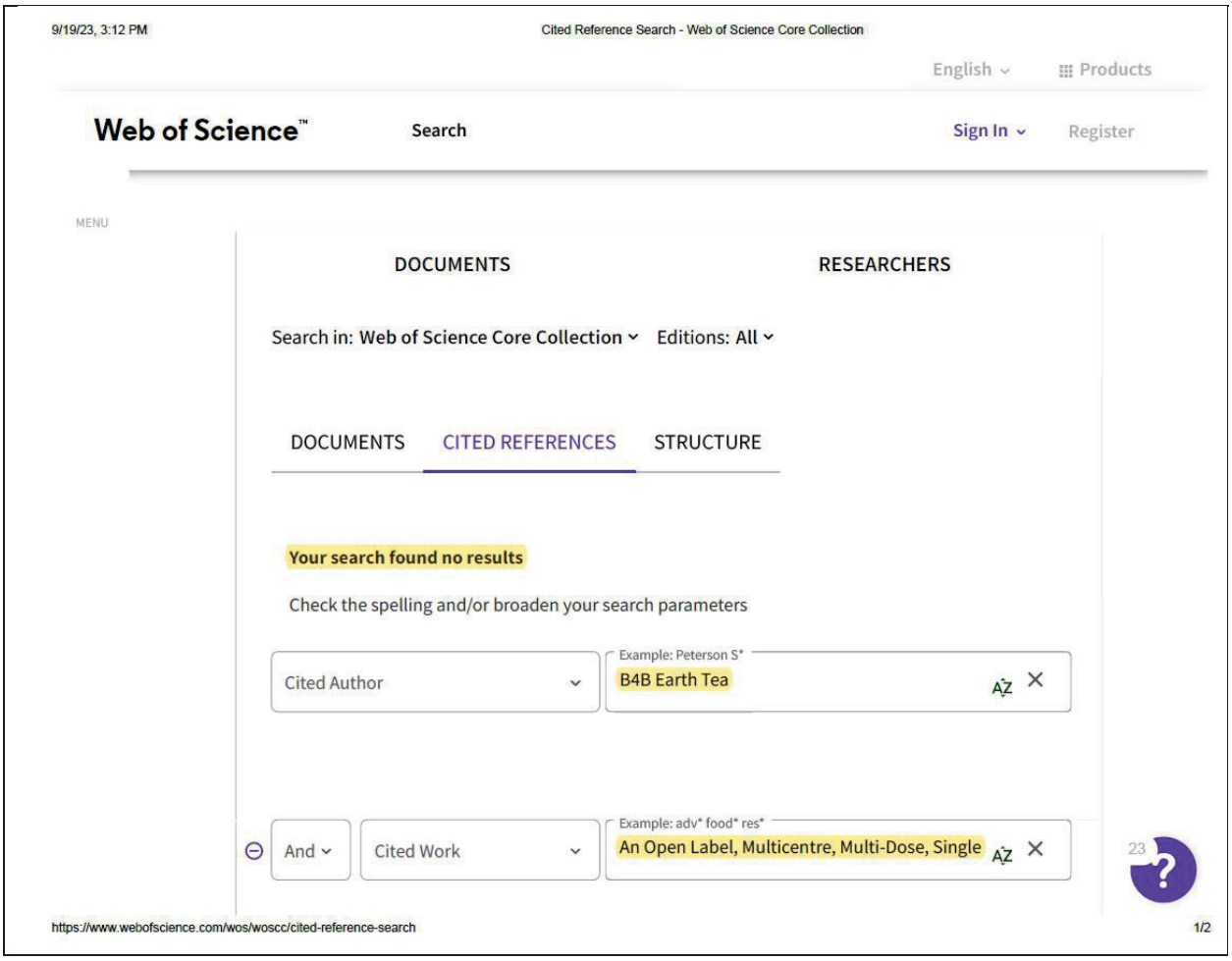

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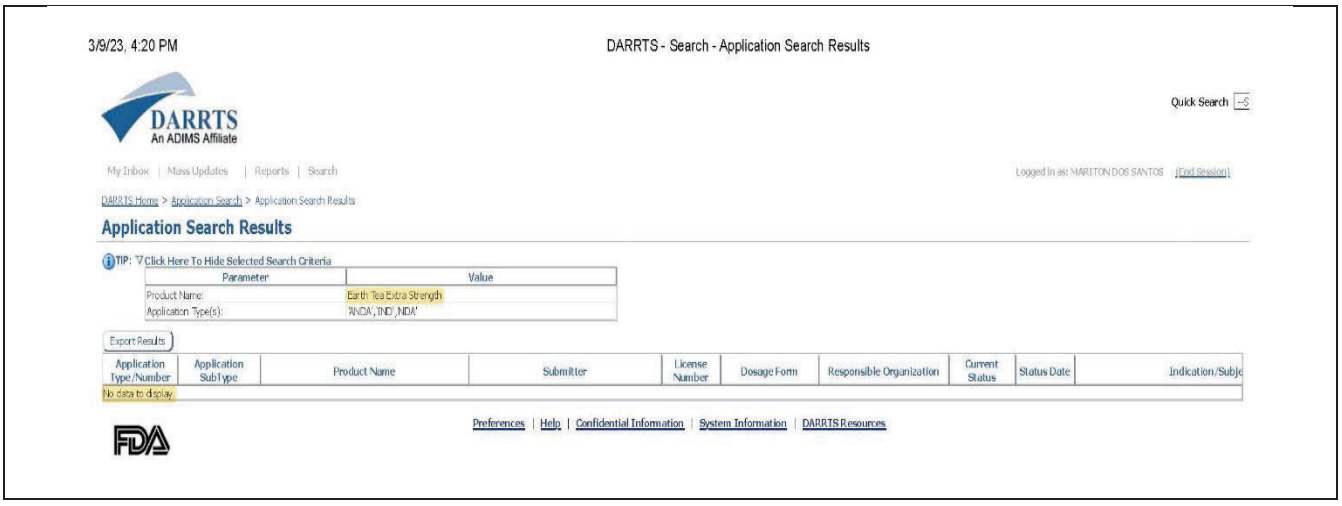

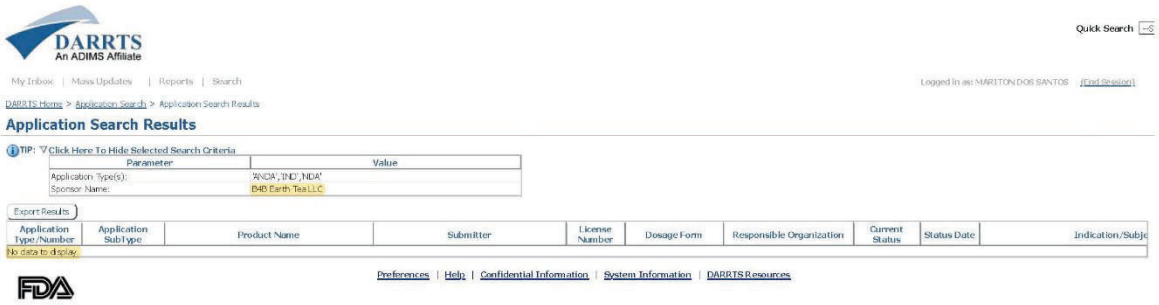
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2f – Drugs@FDA search results:

Search term: "B4B Earth Tea"

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  - Is not marketed in the United States (for example, investigational drugs).

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Search term: "Earth Tea Extra Strength"

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  - Dietary supplements (See Dietary Supplements (https://www.fda.gov/food/dietary-supplements) for more information.)
  - Is approved by FDA's Center for Biologics Evaluation and Research. These FDA-approved drugs are not included in Drugs@FDA. These drugs include vaccines, allergenic products, blood and blood products, plasma derivatives, cellular and gene therapy products, plasma volume expanders, and platelet additive solutions. (See CBER's approved drugs (https://www.fda.gov/vaccines-blood-biologics/biologics-products-establishments).)
  - Is not marketed in the United States (for example, investigational drugs).

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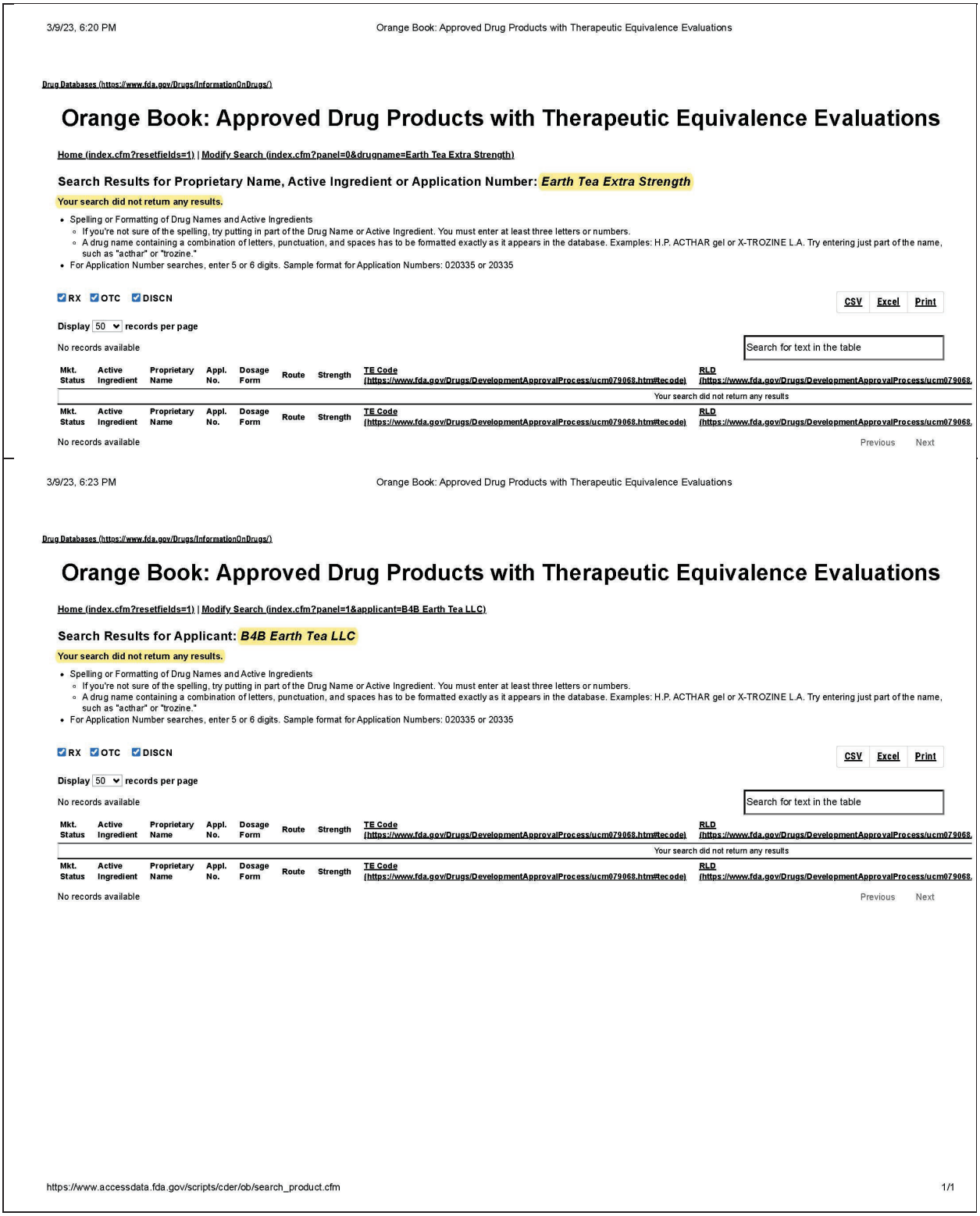

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Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#tecode)	RLD (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.

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ATTACHMENT 3

Mariton Daniel dos Santos, Ph.D.,Pharm.D.
Work: 240-402-2818 • Cell: 443-827-1730 • mariton.dossantos@fda.hhs.gov

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WORK EXPERIENCE

Interdisciplinary Scientist - Senior Biologist **September 2012 – Present**
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Dietary Supplement Programs
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College Park, MD 20740

- Reviewing dietary supplement labels and labeling, claims, safety of dietary ingredients, including providing expert opinions on claims substantiation in support of dietary supplement regulatory actions.

- Preparing GRAS/E memoranda (Generally Recognized as Safe and Effective) in support of FDA regulatory actions.

- Conducting toxicological research for New Dietary Ingredient enforcement, product labeling reviews, and additional research in support of FDA regulatory actions.

- Reviewing dietary supplement labeling products such as 30-day structure-function claim notification; issuing Small Business Nutrition Labeling Exemption and Export Certificates of Free Sale submitted/requested by manufacturers and/or distributors.

Research Physiologist and Pharmacologist **December 2009 – September 2012**
U.S. Army Medical Research Institute of Chemical Defense
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- Investigating central and peripheral mechanisms of toxicity from chemical nerve agents in mammals.

- Implanting wireless biopotential transmitters in rodents to record intrapleural pressure, EMG, EEG, ECG, blood pressure, temperature and activity in rats and guinea pigs.

- Developing vapor in vapor inhalation exposure model for the evaluation of organophosphate toxicity in non-anesthetized rats. Prepared submission of: Development of a Head-Out Vapor Inhalation Exposure Model for the Evaluation of Soman Toxicity in Non-Anesthetized Rats. Michael W. Perkins,

Mariton D. Santos, Benjamin Wong, Alfred M. Sciuto, Gleeson Murphy.

Postdoctoral Fellow **September 2002 – July 2004**
University of Maryland School of Medicine
Department of Anatomy & Neurobiology
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Postdoctoral Fellow **August 2004 – October 2009**
University of Maryland School of Medicine
Department of Neurology
Baltimore, MD 21201

EDUCATION

Federal University of Rio de Janeiro **April 1998 – May 2002**
Rio de Janeiro, BrazilPh.D., Biological Science, August 2002
Magna Cum Laude
Minor emphasis in Neuropharmaco-toxicology
Thesis: "Modulatory actions of anticholinesterasic agents on mammal synaptic transmission"

Federal University of Rio de Janeiro **August 1994 – December 1996**
Rio de Janeiro, Brazil
M.S., Biophysics, December, 1996
Magna Cum Laude
Minor emphasis in Molecular Pharmacology
Thesis: "Evaluation of the mechanisms of action of acetylcholinesterase inhibitors, aldicarb and methamidophos, on muscle nicotinic receptors: single channel currents analysis"

Federal University of Maranhao **January 1988 – December 1992**
Sao Luiz, Brazil
D.Pharm., December 1992
Magna Cum Laude

MONOGRAPHY

Title: Study of the parasitological behavior of the Schistosoma mansoni, isolated from liver of sylvan rodent (*H. braziliensis nanus* THOMAS, 1897) December, 1992.

PUBLICATIONS

1. Sunggu Yang, **Mariton D. Santos**, Cha-Min Tang, Jae Geun Kim and Sungchil Yang A Postsynaptic Role for Short-Term Neuronal Facilitation in Dendritic Spines. *Front. Cell. Neurosci.*, 30 September 2016 | http://journal.frontiersin.org/article/10.3389/fncel.2016.00224/full

2. Benjamin Wong, Michael W. Perkins, **Mariton D. Santos**, Ashley M. Rodriguez, Gleeson Murphy, and Alfred M. Sciuto. Development of a model for nerve agent inhalation in conscious

rats. *Toxicol Mech Methods*, Published online 23 May 2013; Early Online: 1– 11; Online ISSN 1537-6524 (electronic).

3. **Mariton D. Santos**, Michael H. Mohammadi, Sunggu Yang, Conrad W. Liang, Joseph P.Y. Kao, Bradley E. Alger, Scott M. Thompson, Cha-Min Tang. Dendritic Hold and Read: A gated mechanism for short term information storage and retrieval. *PLoS One*. 2012;7(5):e37542

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5. **M.D. Santos**, Edna F.R. Pereira, Yasco Aracava, Newton G. Castro, and Edson X. Albuquerque. Low concentrations of pyridostigmine prevent soman-induced inhibition of GABAergic transmission in the central nervous system: toxicological relevance. *J Pharmacol Exp Ther.* 304(1):254-65. 2003.

6. E.F.R. Pereira, C. Hilmas, **M.D. Santos**, M. Alkondon and E.X. Albuquerque. Unconventional ligands and modulatory of nicotinic receptors. *Journal of Neurobiology* 53(4):479-500, 2002. Review

7. **M.D. Santos**, Manickavasagom Alkondon, Edna F.R. Pereira, Yasco Aracava, Howard L. Eisenberg, Alfred Maelicke, and Edson X. Albuquerque. The nicotinic allosteric potentiating ligand galantamine facilitates synaptic transmission in the mammalian central nervous system. *Molecular Pharmacology* 61:1222-1234, 2002.

8. Pereira EFP, **Santos MD**, Engelhardt E, Calvacanti JLS, Temponi GM e Albuquerque EX. A Galantamine no Tratamento da Doenca de Alzheimer: da pesquisa ao paciente. "Galantamine in the treatment of Alzheimer's disease: from research to the patient" *Revista Brasileira de Neurologia* 37(1):6-12, 2001.

9. E.X. Albuquerque, **M.D. Santos**, M.Alkondon, E.F.R. Pereira and A. Maelicke. Modulation of Nicotinic Report Activity in the Central Nervous System: A Novel Approach to the Treatment of Alzheimer Disease. *Alzheimer Disease and Associated Disorders* 15(1): s19-s25, 2001.

10. Simone R. Chebabo, **M. D. Santos** and Edson X. Albuquerque. The Organophosphate Sarin, at Low Concentrations, Inhibits the evoked Release of GABA in Rat Hippocampal Slices. *NeuroToxicoly* 20(6):871-882, 1999.

11. Edson S. Rocha, **M. D. Santos**, Simone R. Chebabo, Yasco Aracava, and Edson X. Albuquerque. Low Concentrations of the Organophosphate VX Affect Spontaneous and Evoked Transmitter Release from Hippocampal Neurons: Toxicological Relevance of Cholinesterase-Independent Actions. *Toxicology and Applied Pharmacology* 159:31-40, 1999.

12. E.S. Rocha, S.R. Chebabo, **M.D Santos**, Y. Aracava and E.X. Abuquerque. An Analysis of Low Level Doses of Cholinesterase inhibitors in cultured Neurons and Hippocampal Slices of Rats. *Drug and Chemical Toxicology* 21(suppl.1) 191-200, 1998.

13. Camara, A.L., Braga, M.F.M., Rocha, E.S., **Santos, M.D**., Cortes, W.S., Cintra, W.M., Aracava, Y., Maelicke, A. e Albuquerque, E.X. Methamidophos: An anticholinesterase, without significant effects on postsynaptic receptors or transmitter release. *Neurotoxicology*, 18: 589-602, 1997.

SPECIAL LECTURE and WEBINAR

Joint Action Against Products Making Opioid Cessation Claims; CFSAN/FDA – Center Director, Monthly Webcast, February 2018.

Understanding Claims Targeted by FDA During Inspections and Import Entry Reviews; webinar sponsored by the Natural Product Association (NPA), 2015.

Comparative study of the action mechanism of anticholinesterase on muscle nicotinic receptor; Advanced Program of Neuroscience, Federal University of Rio de Janeiro, 1996.

LANGUAGES:

Fluent in Portuguese